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4	BRS	L4	1	6402781.pn. and c at$	USPAT	2003/11/21 15:57	

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2	BRS	L2	8	Langberg.in. and sinus	USPAT	2003/11/21 15:46	

US006537314B2

(12) **United States Patent**
Langberg et al.

(10) **Patent No.: US 6,537,314 B2**
(45) **Date of Patent: Mar. 25, 2003**

(54) **PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT**

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(73) Assignee: **ev3 Santa Rosa, Inc.**, Santa Rosa, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/774,869**

(22) Filed: **Jan. 30, 2001**

(65) **Prior Publication Data**

US.2002/0103533 A1 Aug. 1, 2002

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/494,233, filed on Jan. 31, 2000.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/2.36**; 623/2.37; 623/1.11
(58) **Field of Search** 623/1.11–1.54, 623/1.35, 1.1, 2.1–2.42; 604/509, 510, 96.01, 523, 528, 544, 920

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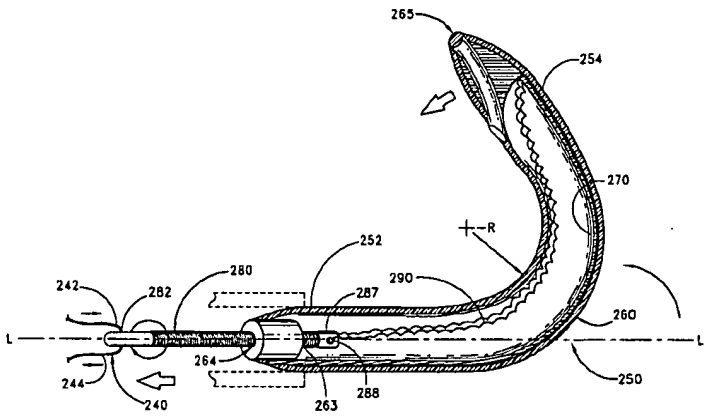
Assistant Examiner—Urmi Chattopadhyay
(74) *Attorney, Agent, or Firm*—Knobb, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A mitral annuloplasty and left ventricle restriction device is designed to be transvenously advanced and deployed within the coronary sinus and in some embodiments other coronary veins. The device places tension on adjacent structures, reducing the diameter and/or limiting expansion of the mitral annulus and/or limiting diastolic expansion of the left ventricle. These effects may be beneficial for patients with dilated cardiomyopathy.

77 Claims, 14 Drawing Sheets



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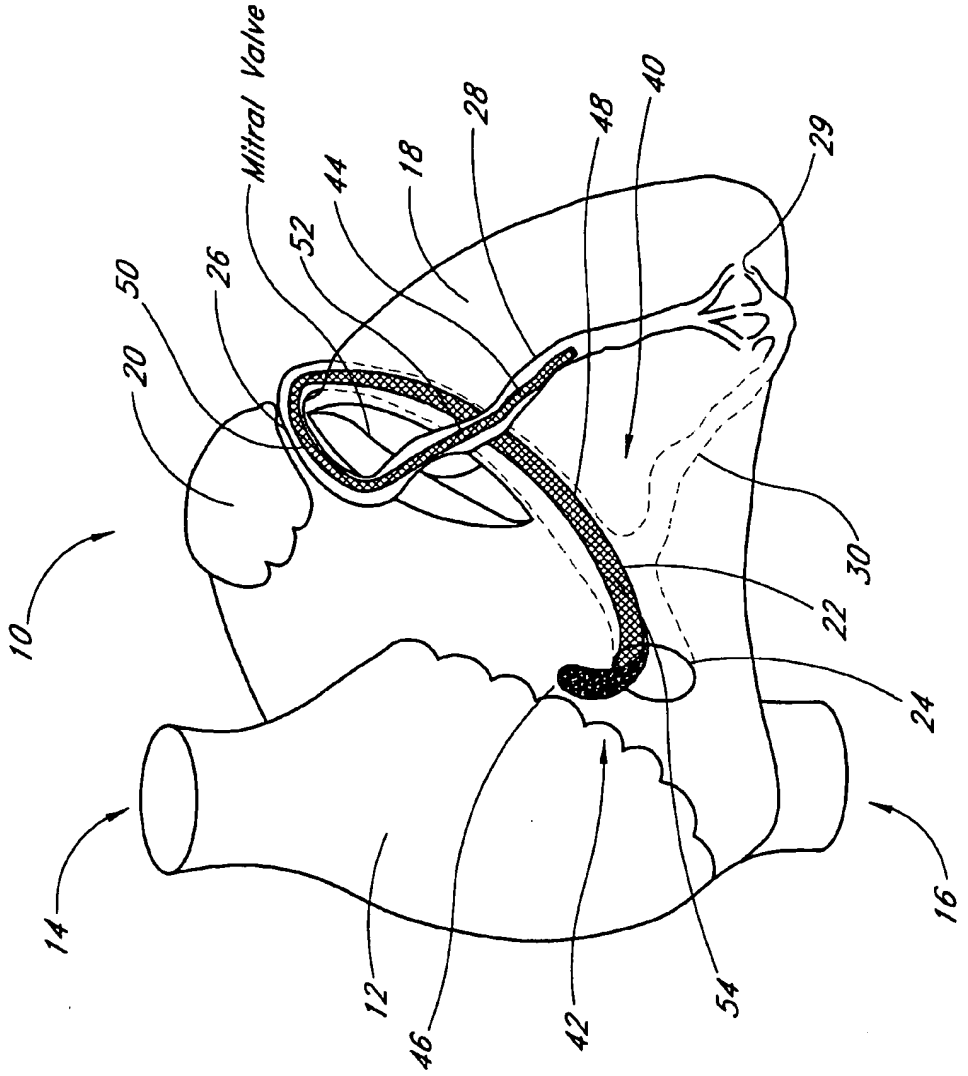
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FIG. 1

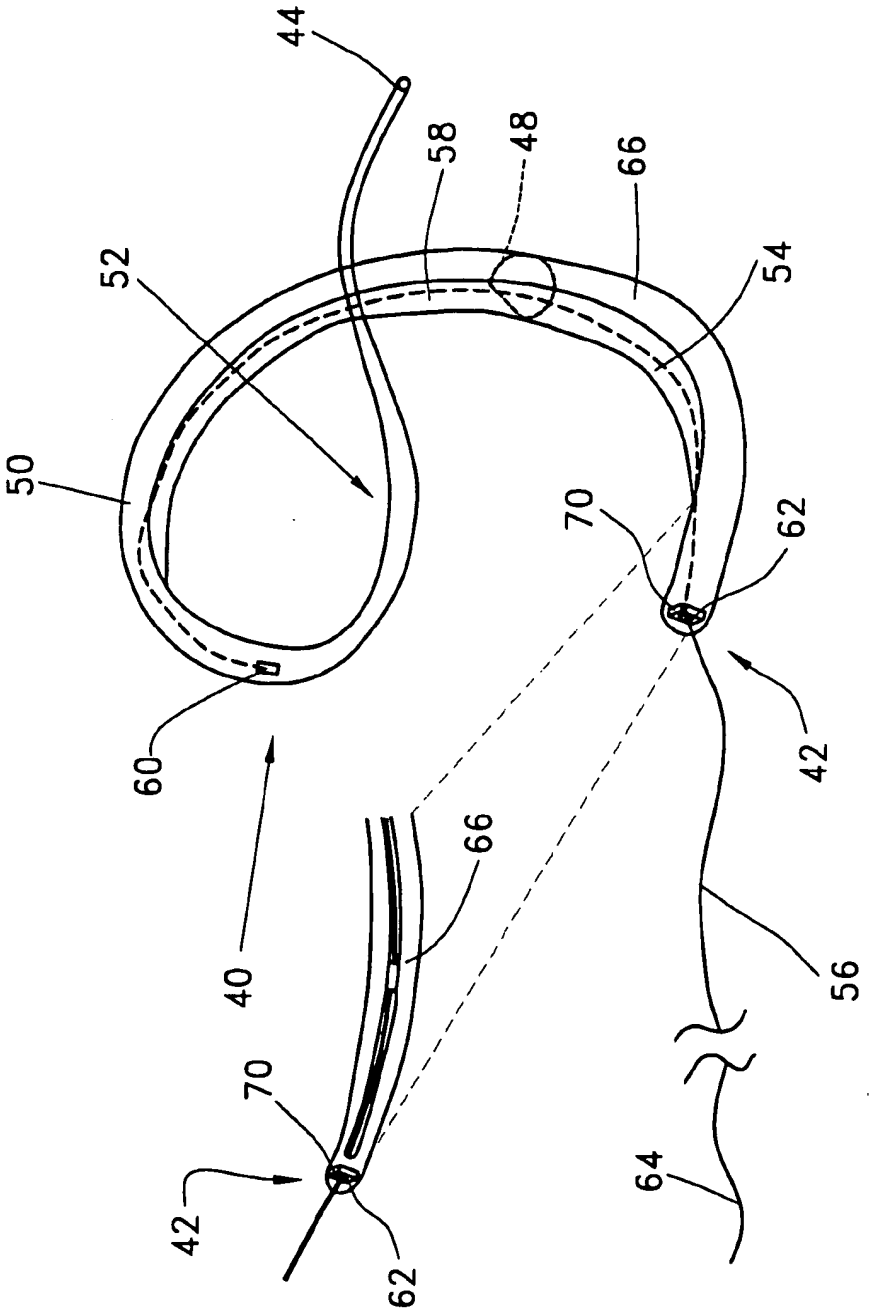

FIG. 2

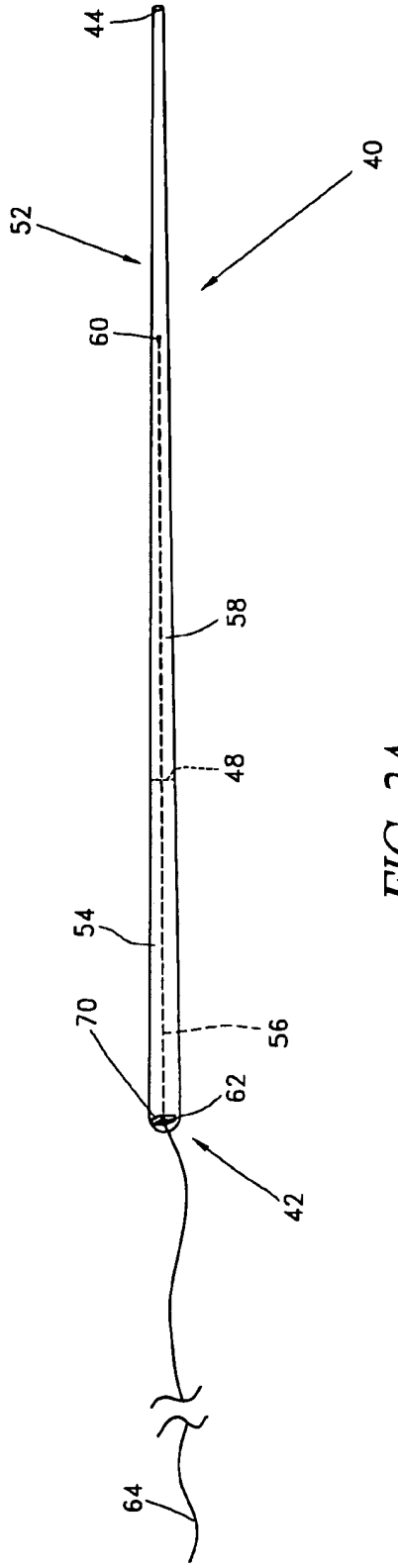

FIG. 2A

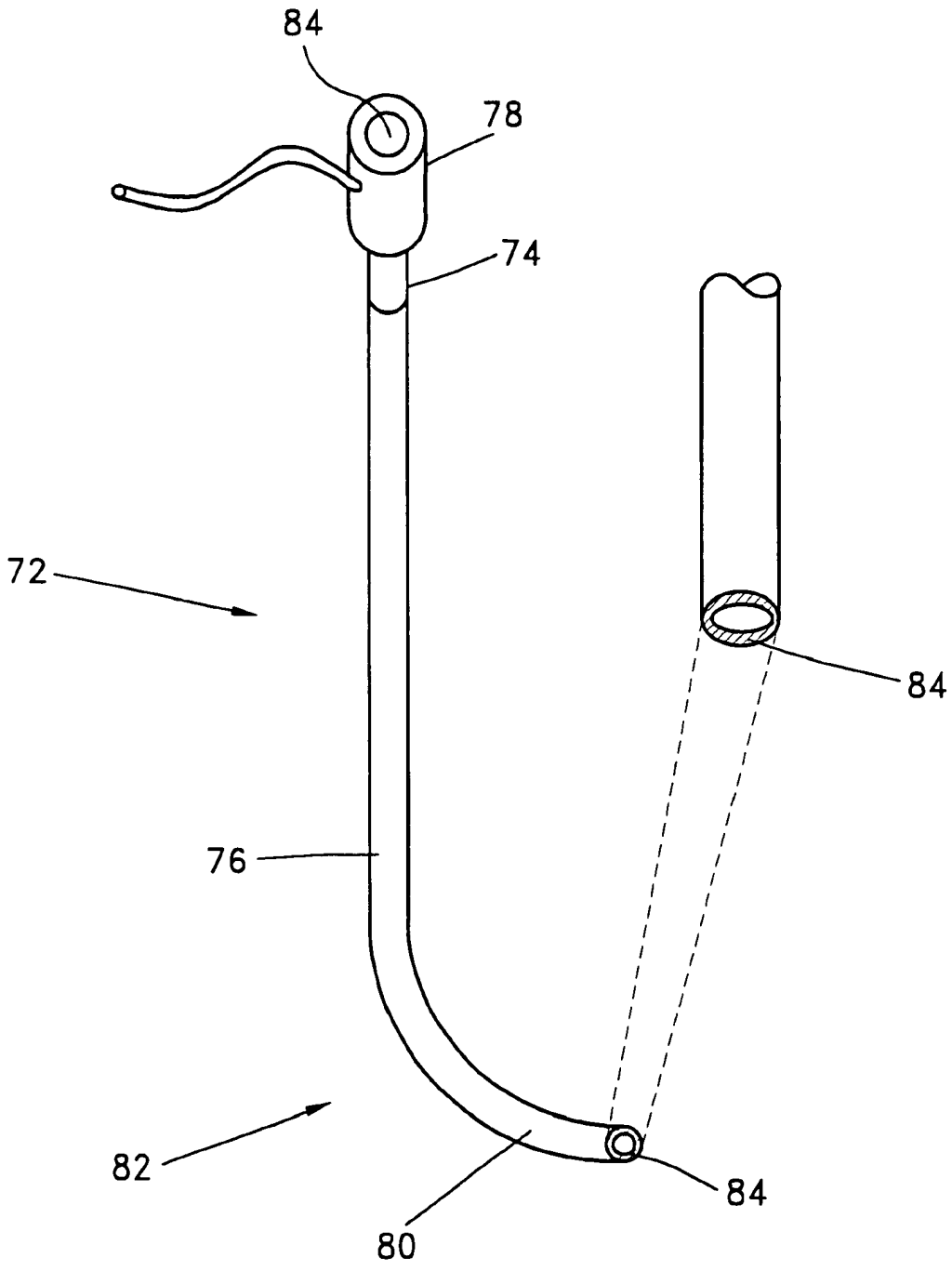

FIG. 3

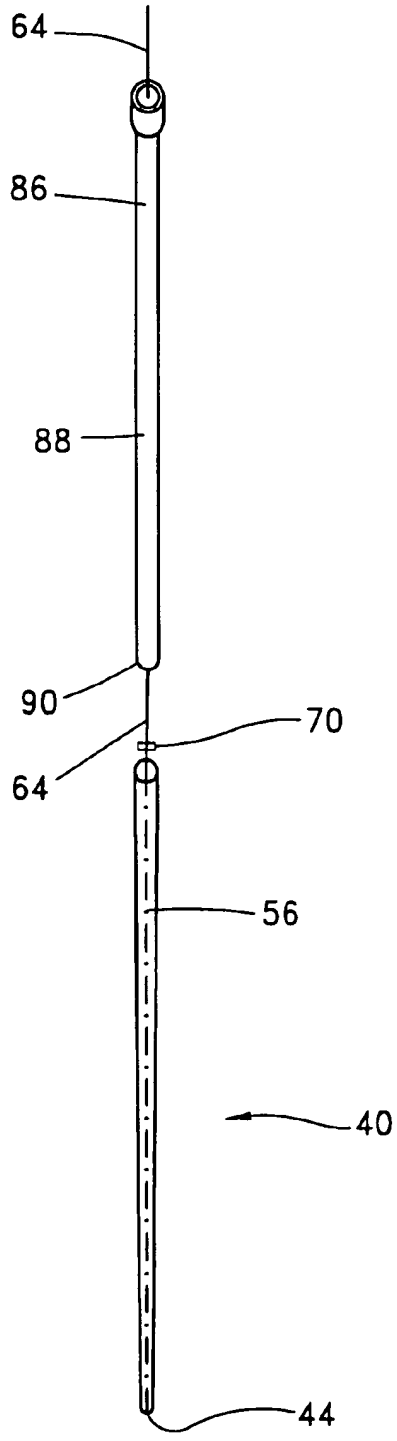

FIG. 4

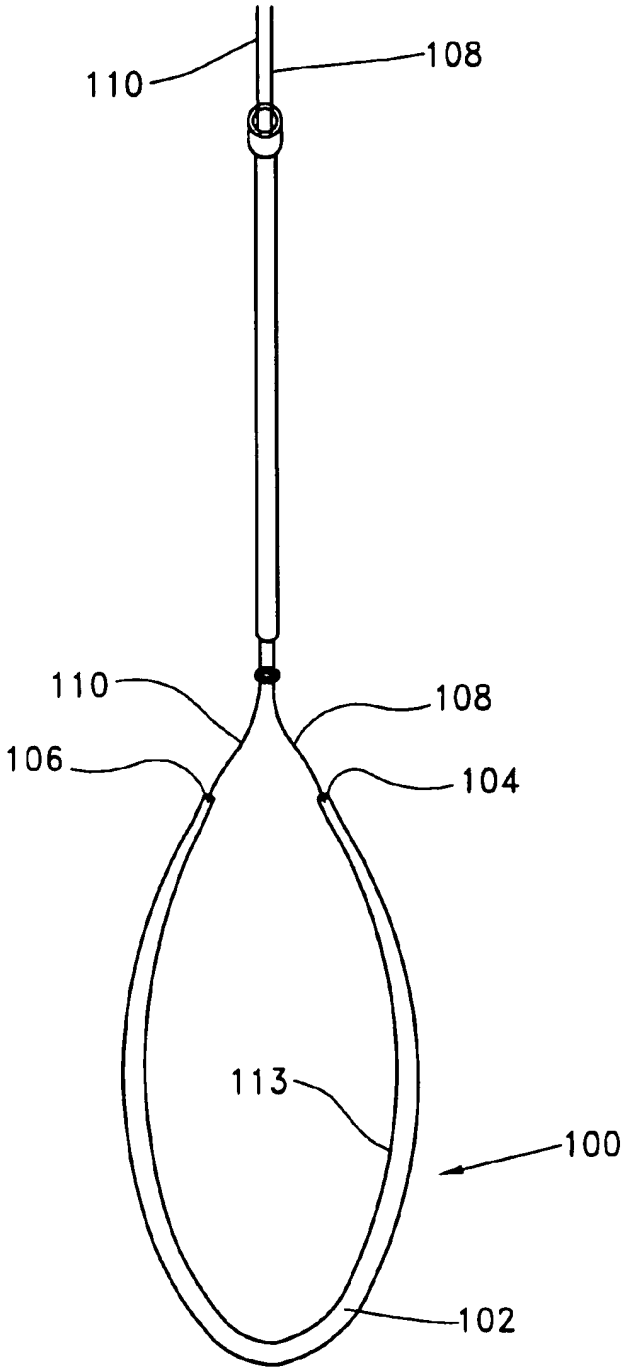

FIG. 5

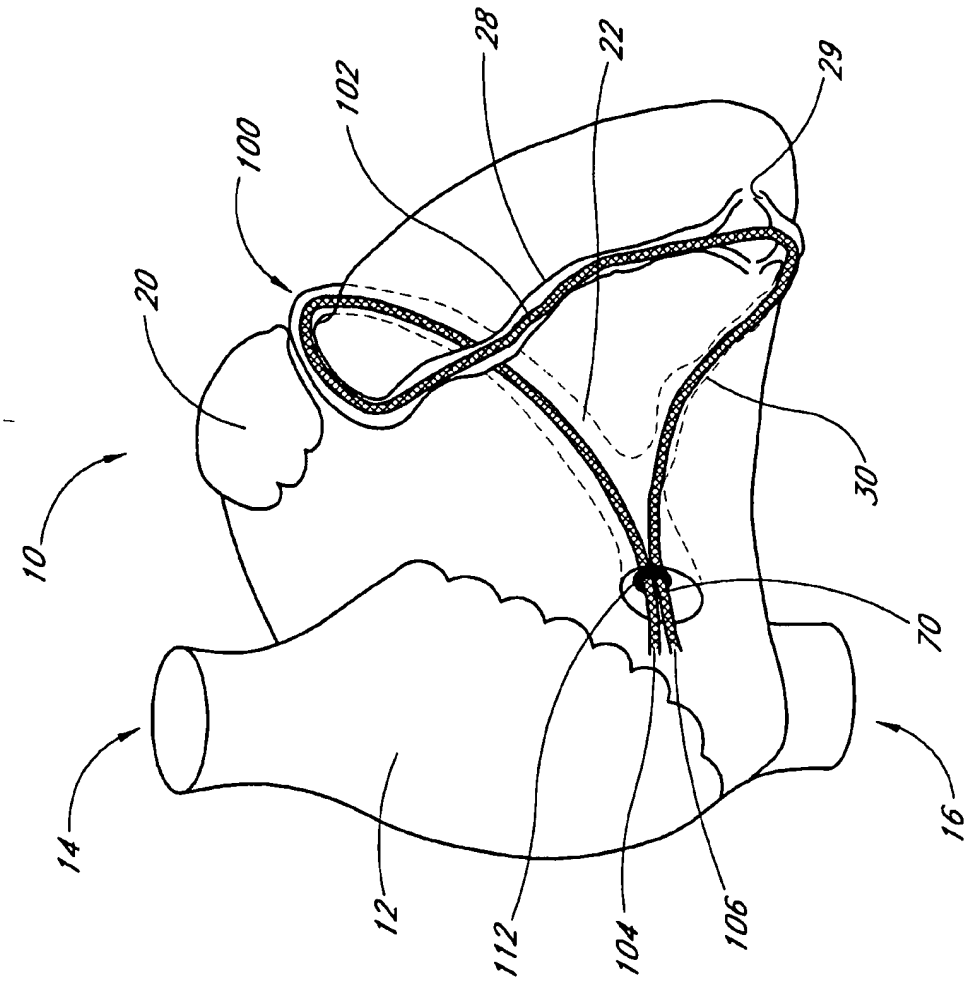

FIG. 6

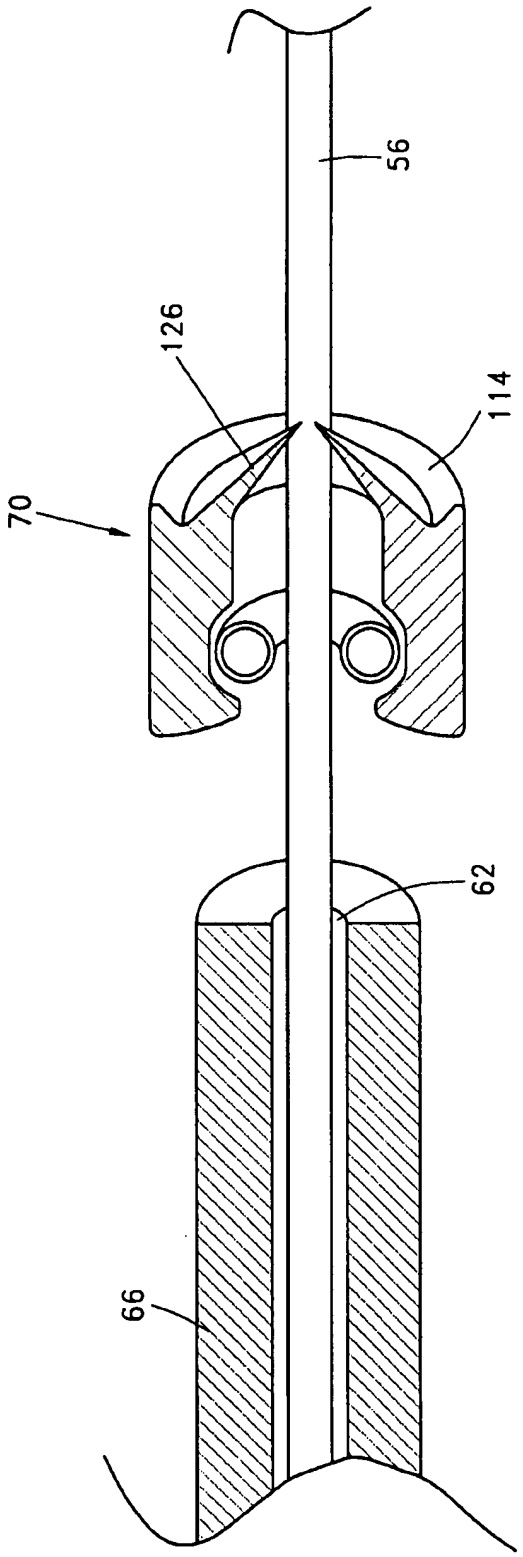

FIG. 7

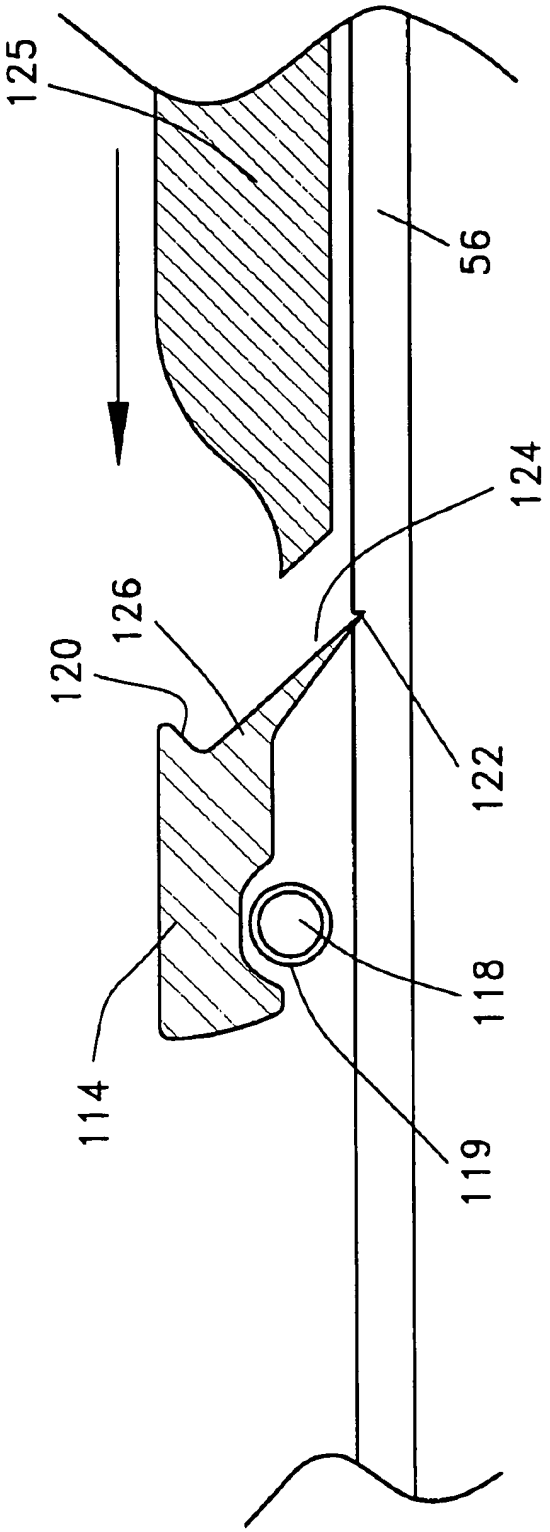

FIG. 8

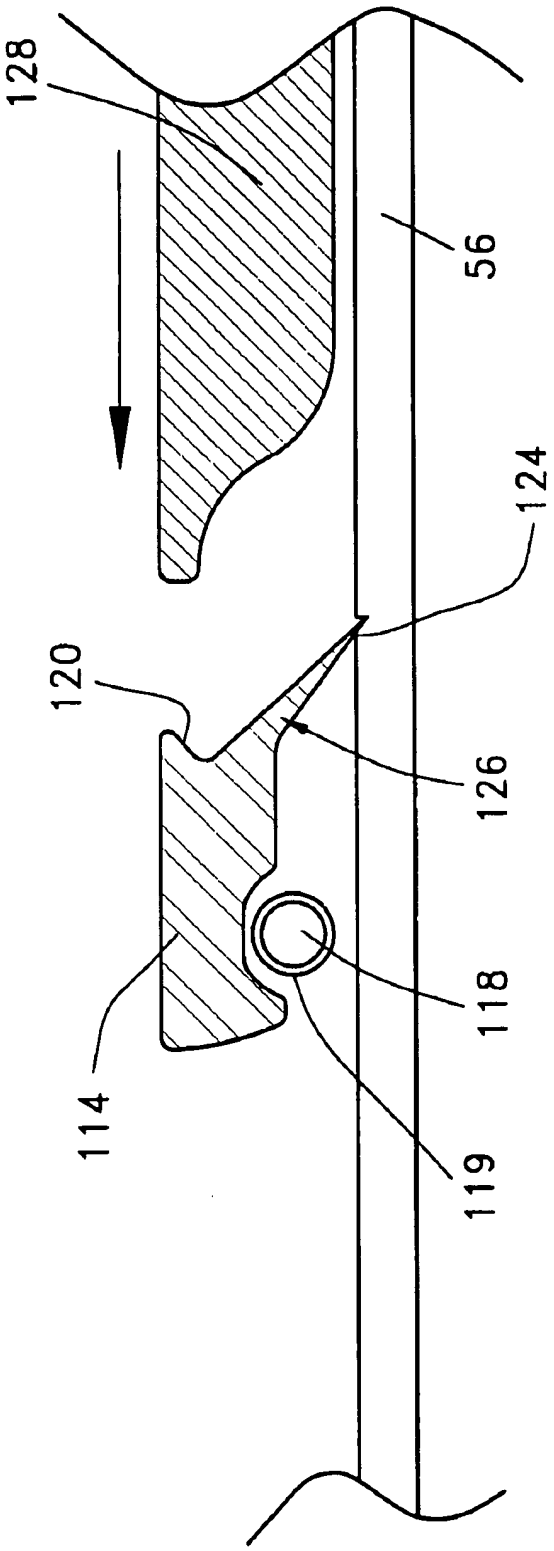

FIG. 9

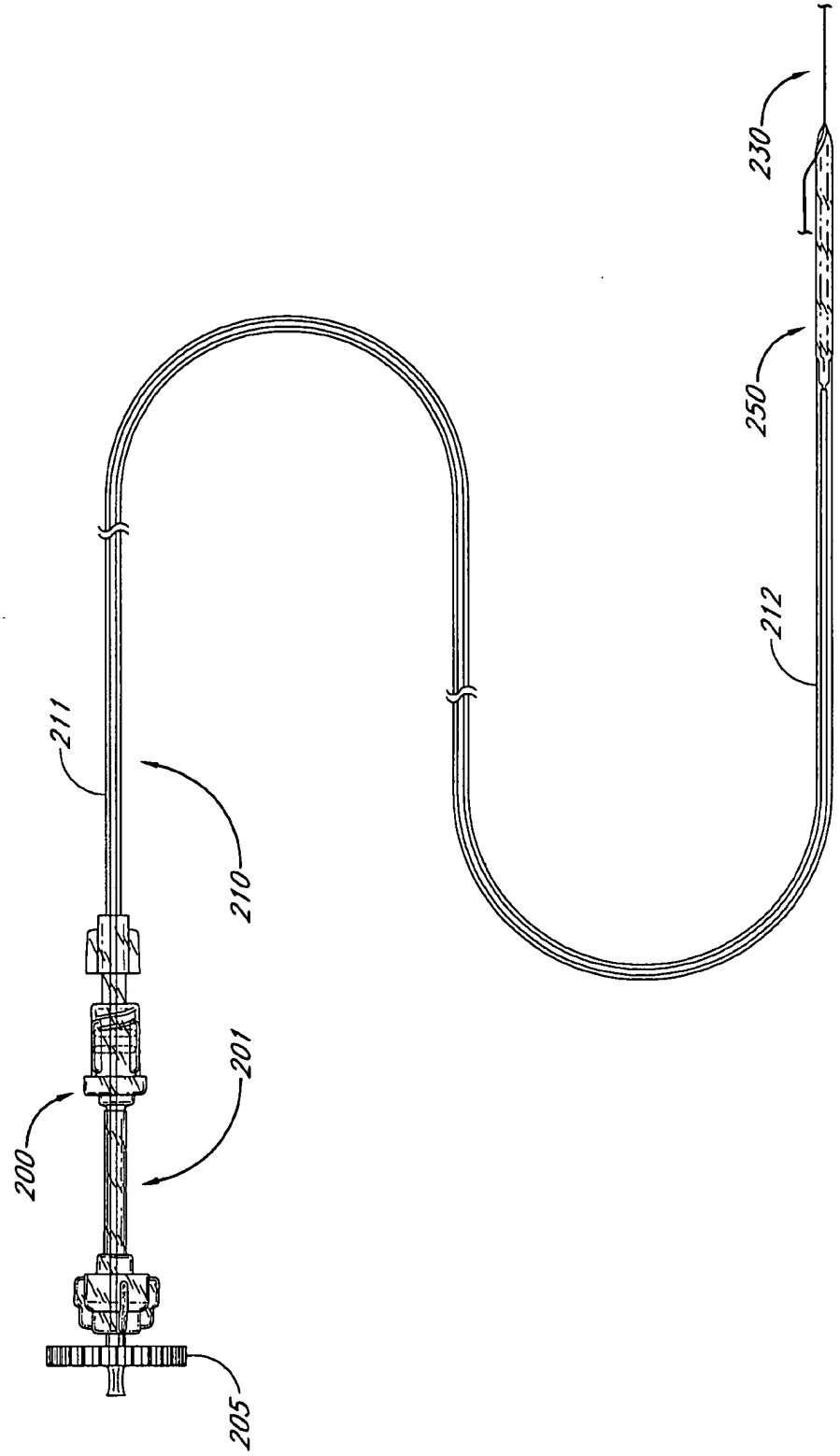

FIG. 10

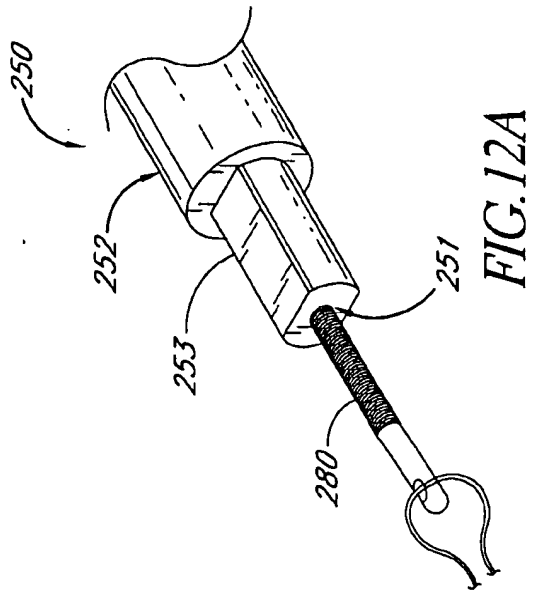

FIG. 12A

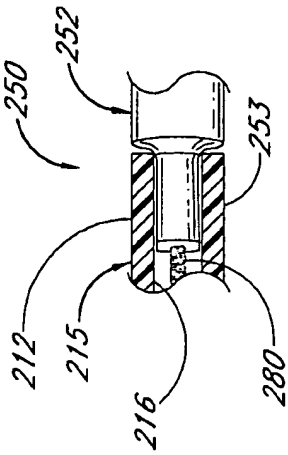

FIG. 12B

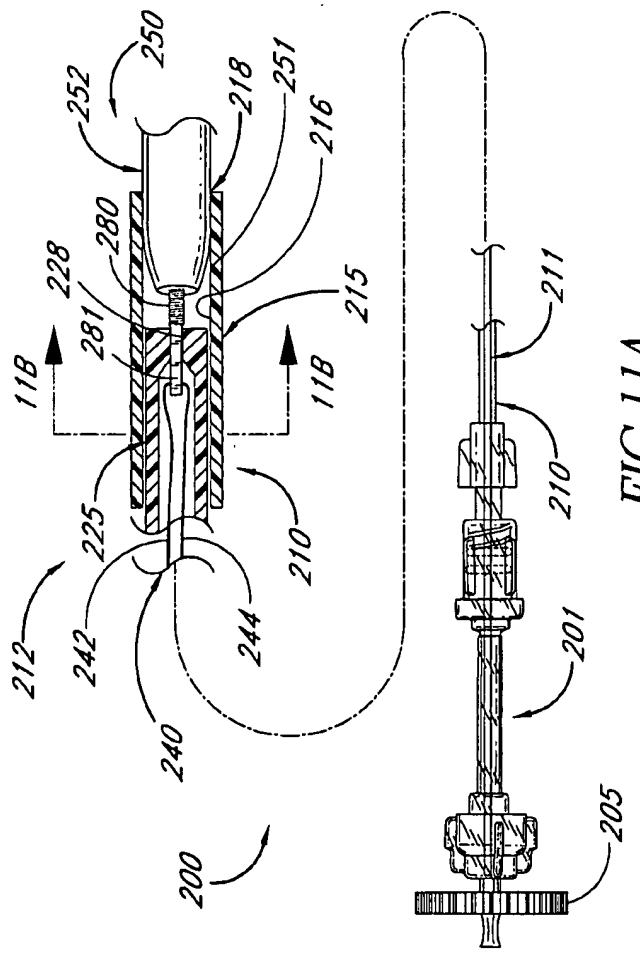

FIG. 11A

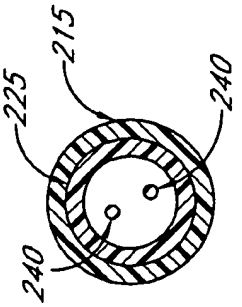

FIG. 11B

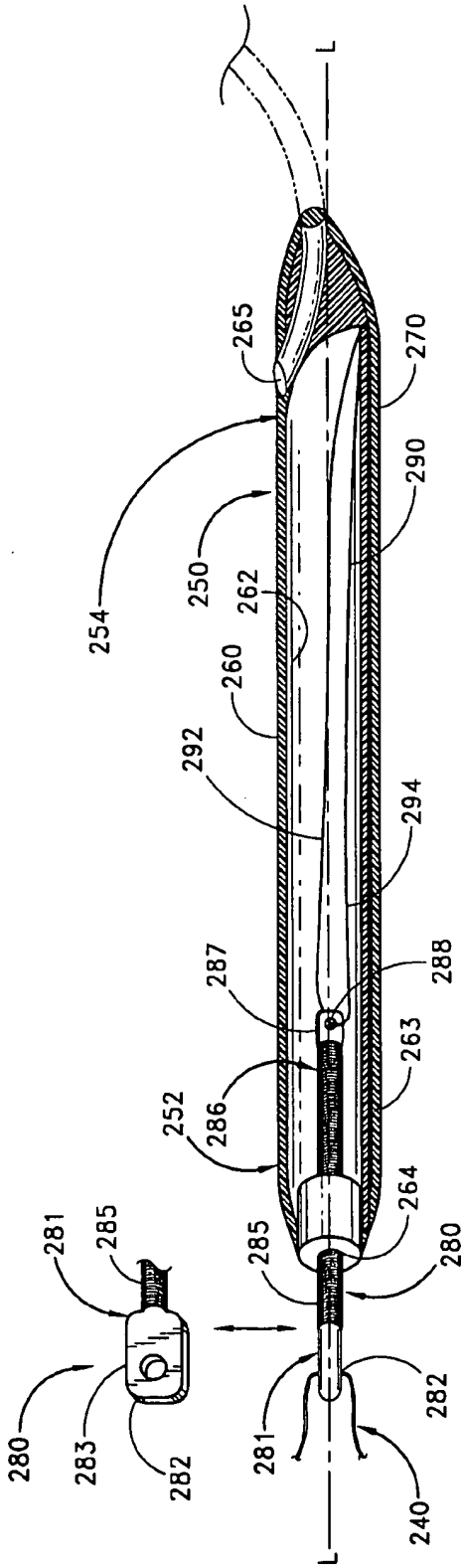
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FIG. 13A

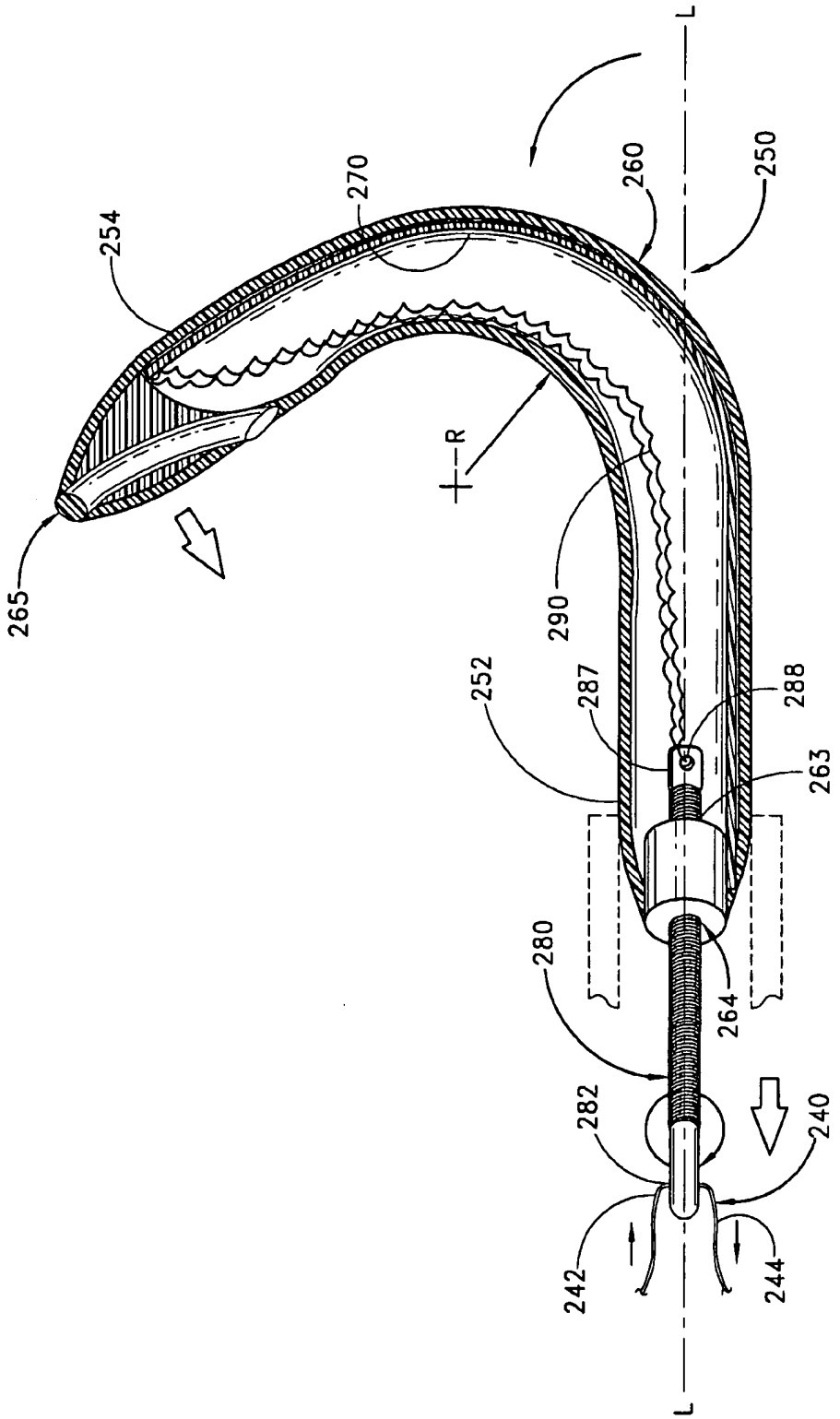
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FIG. 13B

PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT

This application is a continuation-in-part of U.S. application Ser. No. 09/494,233 filed on Jan. 31, 2000, entitled Percutaneous Mitral Annuloplasty and Cardiac Reinforcement.

The present invention relates to intravascular prostheses for remodeling an extravascular anatomical structure. In one application, the present invention relates to a mitral annuloplasty and cardiac reinforcement device which is transluminally implantable in the coronary sinus.

BACKGROUND OF THE INVENTION

Dilated cardiomyopathy occurs as a consequence of many different disease processes that impair myocardial function, such as coronary artery disease and hypertension. The left ventricle enlarges and the ejection fraction is reduced. The resulting increase in pulmonary venous pressure and reduction in cardiac output cause congestive heart failure. Enlargement of the mitral annulus and left ventricular cavity produce mitral valvular insufficiency. This in turn, causes volume overload that exacerbates the myopathy, leading to a vicious cycle of progressive enlargement and worsening mitral regurgitation.

According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques have been developed to repair a diseased or damaged valve. One repair technique which has been shown to be effective in treating incompetence, particularly of the mitral and tricuspid valves, is annuloplasty, in which the effective size of the valve annulus is contracted by attaching a prosthetic annuloplasty ring to the endocardial surface of the heart around the valve annulus. The annuloplasty ring comprises an inner substrate of a metal such as stainless steel or titanium, or a flexible material such as silicone rubber or Dacron cordage, covered with a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. The annuloplasty ring may be stiff or flexible, may be split or continuous, and may have a variety of shapes, including circular, D-shaped, C-shaped, or kidney-shaped. Examples are seen in U.S. Pat. Nos. 4,917,698, 5,061,277, 5,290,300, 5,350,420, 5,104,407, 5,064,431, 5,201,880, and 5,041,130, which are incorporated herein by reference.

Annuloplasty rings may also be utilized in combination with other repair techniques such as resection, in which a portion of a valve leaflet is excised, the remaining portions of the leaflet are sewn back together, and a prosthetic annuloplasty ring is then attached to the valve annulus to maintain the contracted size of the valve. Other valve repair techniques in current use include commissurotomy (cutting the valve commissures to separate fused valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of the valve leaflets or annulus. Annuloplasty rings may be used in conjunction with any repair procedures where contracting or stabilizing the valve annulus might be desirable.

Although mitral valve repair and replacement can successfully treat many patients with mitral valvular insufficiency, techniques currently in use are attended by

significant morbidity and mortality. Most valve repair and replacement procedures require a thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing the two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents. Alternatively, a thoracotomy may be performed on a lateral side of the chest, wherein a large incision is made generally parallel to the ribs, and the ribs are spread apart and/or removed in the region of the incision to create a large enough opening to facilitate the surgery.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta to occlude the aortic lumen between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the ascending aorta, to arrest cardiac function. The patient is placed on extracorporeal cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest in the present application are techniques for the repair and replacement of the mitral valve. The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median sternotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve adjacent to the atriotomy. One of the previously identified techniques may then be used to repair or replace the valve.

An alternative technique for mitral valve access has been used when a median sternotomy and/or rotational manipulation of the heart are inappropriate. In this technique, a thoracotomy is made in the right lateral side of the chest, usually in the region of the fourth or fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

Using such open-chest techniques, the large opening provided by a median sternotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for cannulation of the aorta and/or coronary arteries to induce cardioplegia, manipulation of surgical instruments, removal of excised tissue, and introduction of an annuloplasty ring or a replacement valve through the atriotomy for attachment within the heart.

Mitral valve surgery, including mitral annuloplasty, is usually applied to patients with intrinsic disease of the mitral apparatus. As described above, these patients may have

scarring, retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. Definitive repair requires direct visualization of the valve.

Patients who develop mitral regurgitation as a result of dilated cardiomyopathy do not have intrinsic mitral valve disease. Regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. The ventricle enlarges and becomes spherical, pulling the papillary muscles and chordae away from the plane of the valve and further enlarging the regurgitant orifice. In these patients, correction of the regurgitation does not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus and the sphericity of the left ventricle.

Mitral annuloplasty without repair of the leaflets or chordae has been shown to be effective in patients with dilated cardiomyopathy who are refractory to conventional medical therapy. Bolling and coworkers have operated on a cohort of such patients with New York Heart Association Class III and IV symptoms. Average symptom severity decreased from 3.9 preoperatively to 2.0 after surgery. Hemodynamics and ejection fraction improved significantly. Other investigators have achieved similar results as well. However, the morbidity, risks and expense of surgical annuloplasty are very high in patients with cardiomyopathy and congestive heart failure. Thus, a variety of new techniques for the treatment of congestive heart failure are being explored as adjuncts to drug therapy.

Several cardiac restraint devices have been described. U.S. Pat. No. 5,702,343 to Alfemess discloses a cardiac reinforcement device that is applied as a jacket over the epicardium in order to limit diastolic expansion. However, this requires an open chest operation to implant and does not directly affect the diameter of the mitral annulus. Another approach is disclosed in U.S. Pat. No. 5,961,440 to Schweich, et al., in which tension members are placed through opposite walls of the heart such that they span the ventricle. Less invasive and "minimally" invasive techniques for valve repair and replacement continue to evolve, both on a stopped heart and on a beating heart. These techniques may provide some benefits over open chest procedures, but they are still attended by significant morbidity and mortality risks.

A need therefore remains for methods and devices for treating mitral valvular insufficiency, which are attended by significantly lower morbidity and mortality rates than are the current techniques, and therefore would be well suited to treat patients with dilated cardiomyopathy. Optimally, the procedure can be accomplished through a percutaneous, transluminal approach, using simple, implantable devices which do not depend upon prosthetic valve leaflets or other moving parts.

SUMMARY OF THE INVENTION

The invention according to one mode is a medical system with a medical device for remodeling a tissue structure adjacent to a body space that is defined at least in part by a tissue wall in a patient. The medical device has a prosthesis that in a first configuration having a first shape is adapted to be delivered into and positioned at least in part within the body space. The prosthesis is thereafter adjustable within the body space to a second configuration having a second shape that is adapted at least in part to exert a force from within the body space onto the adjacent tissue structure in order to remodel the adjacent tissue structure.

According to one beneficial mode of this aspect wherein the adjacent tissue structure has a wall that circumscribes a space having a diameter, the prosthesis when adjusted from the first configuration to the second configuration within the body space is adapted to compress the adjacent tissue structure to thereby reduce its diameter.

The invention according to another aspect is a medical system with a medical device for remodeling an extravascular tissue structure adjacent to a vessel in a patient. The device has a prosthesis that in a first configuration having a first shape is adapted to be delivered into and positioned at least in part within the vessel. The prosthesis is thereafter adjustable within the vessel to a second configuration having a second shape and is adapted to thus exert a force from within the vessel onto the extravascular tissue structure in order to remodel the extravascular tissue structure.

The invention according to another aspect is a medical system with a medical device for remodeling a mitral valve annulus from within a coronary sinus in a patient. The prosthesis is adapted to be positioned in the first configuration at least in part within a coronary sinus and is adapted to remodel a mitral valve annulus adjacent to the coronary sinus when the prosthesis is located at least in part within the coronary sinus and is adjusted to the second configuration. This aspect is particularly beneficial for use in performing mitral valve annuloplasty and treating mitral valve insufficiency.

According to one highly beneficial mode for these various system aspects of the invention just provided, the prosthesis is an elongate body that extends between proximal and distal ends.

The following are further beneficial embodiments and related applications for this mode with respect to a an elongate body for use according to the aspect of the mitral valve remodeling aspect of the invention. Such further embodiments are also generally considered to be beneficially applicable to the other medical system aspects just described for the invention with respect to the prostheses constructed for remodeling operation generally from within a body space or more specifically from within a vessel, respectively, and in particular without limitation with respect to the mode wherein the respective prosthesis is an elongate body. The following embodiments and applications are considered to be independently beneficial, and are not generally considered mutually exclusive or reliant unless expressly described as such.

In one such further embodiment, the elongate body is adapted to be permanently implanted in the patient at least in part within the coronary sinus in the second configuration in order to provide chronic remodeling of the mitral valve annulus.

In another further embodiment, the device further includes a guidewire tracking member such as a guidewire lumen that is adapted to track over a guide wire in order to position the elongate body within the coronary sinus.

According to another further embodiment, the elongate body is selectively adjustable between the first and second configurations while the elongate body is located at least in part within the coronary sinus. The elongate body is adapted to be temporarily implanted at least in part within the coronary sinus in the second configuration for temporary remodeling of the mitral valve annulus and to be thereafter removed from the coronary sinus in the first configuration.

In still another further embodiment, the elongate body within the coronary sinus comprises a substantially similar length between the first and second configurations.

In still another further embodiment, the elongate body within the coronary sinus is relatively non-expandable while

the elongate body is adjusted between the first and second configurations. In another further embodiment, the elongate body within the coronary sinus is relatively non-compressible while the elongate body is adjusted between the first and second configurations.

According to a further embodiment, the elongate body has a length between its respective proximal and distal ends that is less than about 10 cm.

In yet a further embodiment, the device further includes a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus.

In yet a further embodiment, in the second configuration the second shape for the elongate body at least within the coronary sinus defines an arc.

In a further embodiment, the device further includes an anchor for retaining the elongate body at least in part within the coronary sinus. In one application, the anchor is provided at a region along a distal portion of the elongate body. In another application, the anchor provides a friction enhancing surface for engaging a wall of the coronary sinus. In another application, the anchor may have at least one barb for piercing a wall of the coronary sinus.

In further applications of the anchor embodiment, the anchor may be provided at the proximal or distal end of the elongate body, or multiple anchors may be provided. One such application provides a proximal anchor that is adapted to be positioned outside of the coronary sinus and against a wall of the right atrium in order to anchor the elongate body at least in part within the coronary sinus. Another such application is a distal anchor that is adapted to be positioned within the great cardiac vein when the elongate body is located at least in part within the coronary sinus.

In still a further embodiment, a forming element is secured to the elongate body at a point of attachment and that is moveable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations.

In one highly beneficial application of this embodiment, the forming element between the point of attachment and the proximal end of the elongate body is substantially circumferentially confined by the elongate body. This may be achieved in a further beneficial example by providing the forming element within a substantially tubular wall or other radially confining housing of the elongate body.

In another highly beneficial application, the forming element has a proximal extension that extends proximally from the elongate body and externally of the patient when the elongate body is located at least in part within the coronary sinus, and the elongate body within the coronary sinus is adjustable within the coronary sinus from the first configuration to the second configuration by manipulating the proximal extension outside of the patient.

In another application wherein an anchor is provided for retaining at least a portion of elongate body within the coronary sinus, and the axial length of the elongate body between the anchor and the point of attachment of the forming element to the elongate body is within the range of from about 2 cm to about 8 cm. In still another application, an annuloplasty zone is provided on a proximal portion of the body that is adapted to be positioned within the coronary sinus for annuloplasty via the coronary sinus, and an anchor zone is provided on a distal portion of the body. The forming element is attached to the body between a mid-point of the annuloplasty zone and a mid-point of the anchor zone, such that force imparted from the forming element at the point of attachment with respect to the proximal end of the body deflects at least a portion of the annuloplasty zone into an arcuate configuration.

In still another particularly beneficial application of the forming element embodiment, the elongate body is adjustable from the first configuration to the second configuration principally by applying a force from the forming element to the elongate body.

In one more detailed application, wherein the elongate body is adjustable from the first configuration to the second configuration principally by transmitting an axial force from the forming element onto the elongate body relative to the longitudinal axis of the embodiment. In still further detail to this application, the elongate body may be adjustable from the first configuration to the second configuration in response to proximal retraction of the forming element. In another regard, the elongate body may be movable from the first configuration to the second configuration in response to distal advancement of the forming element. In the alternative or in addition to these axial force applications, the forming element may be adapted to adjust the elongate body from the first configuration to the second configuration at least in part by providing a rotational force along at least a portion of the forming element. In one regard, the forming element according to this rotational application may include a rotational force transmission member coupled to an axial force transmission member via a rotational coupler such that rotational forces are converted to axial forces to deflect the elongate body.

In a particularly beneficial further application of the forming element embodiment, the elongate body is adapted to be uncoupled in the second configuration from at least a portion of the forming element as a permanent implant located at least in part within at least the coronary sinus. This may be accomplished by adapting the forming element to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration. In one regard, a cutting tool may be provided that is adapted to cut the forming element while the elongate body is positioned at least in part within the coronary sinus. In another regard, the forming element includes proximal and distal members that are detachably engaged in a manner that allows for force transmission from outside the body of the patient to an attachment point to the elongate body, and also for the members to be uncoupled to leave the elongate body and distal member within the patient as a device implant.

In another particularly beneficial further application of the forming element embodiment, the medical device further includes a lock that is adjustable between disengaged and engaged configurations. The disengaged configuration allows the forming element to be moveable relative to the elongate body in order to adjust the elongate body from the first configuration to the second configuration at least in part within the coronary sinus. The engaged configuration engages the forming element to substantially fix the forming element relative to the elongate body when the elongate body is in the second configuration at least in part within the coronary sinus. In a particular application that is highly beneficial for selective adjustment of the elongate body between first and second configurations, the lock is selectively adjustable between the engaged and disengaged configurations. In another beneficial application, locking and/or unlocking tools may also be provided in order to adjust the lock from the disengaged configuration to the engaged configuration, or visa versa, respectively.

In another further beneficial embodiment of the medical system aspect of the invention, a deployment system is

provided that cooperates with the elongate body in order to deliver the elongate body or prosthesis in the respective first configuration and shape to the desired location for subsequent operation for tissue remodeling. In one particularly beneficial further detailed embodiment, the deployment system includes at least in part a delivery member that is coupled to the elongate body or prosthesis and is adapted to advance the elongate body or prosthesis into the coronary sinus.

The invention according to another aspect is a method for providing a medical device for use in treating a patient from within a vein that is associated with the patient's heart. The method according to this aspect includes providing an array of medical devices, each having a prosthesis or elongate body that is adjustable in-situ from a first configuration having a first shape to a second configuration having a second shape. Each elongate body of each medical device of the array is constructed to have a unique size relative to the elongate bodies of the other medical devices of the array. This method aspect also includes choosing the medical device from the array at least in part based upon a known measurement for a vein that is associated with the patient's heart. A comparison between the measurement of the vein with the unique size for the elongate body of the chosen medical device provides indicia that the unique size is appropriate for being delivered in the first configuration into the patient's respective vein and for being adjustable within the vein from the first configuration to the second configuration in order to remodel the mitral valve annulus from within the vein.

According to one mode of this aspect, the medical device is chosen at least in part based upon a known measurement for a coronary sinus. According to another mode wherein the vein has a central axis, the known measurement comprises at least one of: a length of at least a portion of the vein, a radius of curvature of the vein along the central axis, and a diameter of the vein across the central axis.

This aspect may be further modified according to another aspect of the invention to include providing the array of devices such that each device is constructed to have at least one unique geometry relative to the elongate bodies of the other medical devices. This method aspect further includes choosing the medical device from the array at least in part based upon a known measurement for a parameter associated with at least one of (i) a valve associated with the patient's heart, and (ii) a vessel associated with the patient's heart.

A beneifical mode of this aspect allows the medical device to be chosen from the array at least in part based upon a known measurement for a geometric parameter associated with at least one of the mitral valve and the coronary sinus. With respect to choosing the medical device at least in part based upon a known measurement for a geometric parameter associated with the mitral valve, such geometric parameter may be directly or indirectly associated with a mitral valve annulus of the mitral valve, and may in one particular further embodiment be a diameter of the mitral valve annulus.

There is provided in accordance with one aspect of the present invention, a method of treating mitral valvular insufficiency. The method comprises the steps of tranvenously advancing a prosthesis into the coronary sinus, and deploying at least a portion of the prosthesis within the coronary sinus to reduce the diameter of the mitral annulus. Although deployment can be accomplished in an open surgical procedure, the method preferably further comprises the step of percutaneously accessing the venous system prior to the transluminally advancing step. The venous system may be accessed by one of the internal jugular, subclavian, or femoral veins. Preferably, the deploying step further includes the step of advancing the prosthesis from a first configuration for transluminal implantation to a second configuration to apply pressure to the wall of the coronary sinus and thereby reduce and/or restrain the diameter of the mitral valve annulus.

In accordance with another aspect of the present invention, there is provided a method of performing transluminal mitral annuloplasty. The method comprises the steps of providing a catheter which carries a prosthesis, and percutaneously inserting the catheter into the venous system. The prosthesis is transluminally advanced into the coronary sinus, and deployed in the coronary sinus to influence the size of the mitral valve annulus. Preferably, the prosthesis is caused to exert a compressive force on the mitral valve annulus.

The compressive force of one embodiment is generated by a bias in the prosthesis. In an alternate embodiment, the compressive force is generated by tightening the prosthesis around the mitral valve annulus following the transluminally advancing step. The tightening step may be accomplished by axial movement of a tightening element with respect to the prosthesis.

In accordance with a further aspect of the present invention, there is provided a method of providing a therapeutic compressive force against a tissue structure which is distinct from a vessel wall. The method comprises the steps of positioning a device in the vessel, and exerting a force against the wall of the vessel to exert a force against an extravascular tissue structure. Preferably, the positioning step is accomplished percutaneously. In one application, the extravascular tissue structure comprises the mitral valve annulus. Thus, the present invention provides a method of performing annuloplasty of the mitral valve, comprising positioning a prosthesis in the venous sinus.

In accordance with a further aspect of the present invention, there is provided a method of treating a mitral valve. The method comprises the steps of providing an elongate flexible vascular implant, having a first attachment site spaced axially apart from a second attachment site. The first attachment site is transluminally advanced through the coronary sinus and coronary venous system to form the implant into an open loop. The open loop is reduced in size to place tension on the coronary sinus, and the first attachment site is attached to the second attachment site to close the loop and retain tension on the coronary sinus.

In accordance with another aspect of the present invention, there is provided a method of treating the heart. The method comprises the steps of advancing an implant through an access site and into a coronary vein such as the coronary sinus. A forming element on the implant is thereafter proximally retracted while resisting proximal movement of the implant, thereby forming the implant into a desired shape. The access site is thereafter closed, leaving the formed implant within the coronary vein.

Preferably, the method further comprises the step of locking the implant into the desired shape prior to the closing step. The method may additionally comprise the step of severing at least a portion of the forming element prior to the closing step.

A further aspect of the invention is a medical system with a transluminally implantable device for limiting diastolic expansion of the left ventricle. This device includes an elongate body having a proximal end and a distal end. A first

attachment site is provided proximate the distal end of the elongate body and a second attachment site proximate the proximal end of the elongate body. The first and second attachment sites are adapted to be secured together. In one mode of this aspect, the elongate body is flexible a locking clip is provided for securing the ends. The body adapted to loop through the coronary venous system, and the locking clip is adapted to cinch onto the proximal end and distal end of the flexible elongate body until a requisite amount of tension is produced to limit diastolic expansion of the left ventricle.

Further features and advantages of the present invention will become apparent to those of ordinary skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of the heart, showing one embodiment of the mitral annuloplasty device of the present invention deployed within the coronary venous system.

FIG. **2** is a schematic illustration of the mitral annuloplasty device shown in FIG. **1**.

FIG. **3** is an overall view and cross-sectional view through a transvenous delivery sheath.

FIG. **4** is a schematic illustration of the delivery sheath and two different embodiments of the implant for extravascular remodeling, one with a forming element and one without.

FIG. **5** is a schematic illustration of an alternative embodiment of the present invention positioned in an open-loop configuration through the delivery sheath.

FIG. **6** is a schematic illustration of a heart, having an alternate embodiment of the mitral annuloplasty and cardiac reinforcement device of the present invention positioned within the coronary sinus and contiguous venous system.

FIG. **7** is a schematic cross-sectional view of one embodiment of a locking device in accordance with the present invention.

FIG. **8** is a fragmentary view of a portion of the lock illustrated in FIG. **7**, with a locking tool.

FIG. **9** is a fragmentary view as in FIG. **8**, showing an unlocking tool.

FIG. **10** is a perspective view of another device assembly according to the invention.

FIG. **11A** is a segmented view of the device assembly shown in FIG. **10**, and shows a partially exploded view of a region of the assembly.

FIG. **11B** shows a transverse cross-sectional view taken along **11B—11B** in FIG. **11A**.

FIG. **12A** shows an exploded perspective view of one region of another device assembly according to the invention.

FIG. **12B** shows a partially cross-sectioned side view of a region of a device assembly similar to that shown in FIG. **12**.

FIG. **13A** shows a partially cross-sectioned exploded side view of a distal prosthetic implant region of a device assembly similar to that shown in FIG. **10**, and shows the distal prosthetic implant region in a first configuration during a first mode of use.

FIG. **13B** shows a similar view as that shown in FIG. **13A**, and shows the distal prosthetic implant region in a second configuration during a second mode of use.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention provides a method and apparatus for performing mitral annuloplasty and remodeling of the left ventricle using a device that may be introduced percutaneously, and placed within the coronary venous system of the heart. The device exerts compressive force on the mitral annulus and left ventricle, reducing the severity of mitral regurgitation and the size of the left ventricular cavity. The device thus enables reduction of the mitral annulus and constraint of the diastolic expansion of the left ventricle yet without the morbidity and other risks associated with open chest surgery.

The present inventors have determined that the coronary sinus and veins provide an ideal conduit for the positioning of an intravascular prosthesis for remodeling the mitral annulus, since they are positioned adjacent the mitral annulus and interventricular septum. The coronary sinus is contained within the atrioventricular groove, and is in close proximity to the posterior, lateral and anterior aspects of the mitral annulus. The coronary sinus and coronary veins are cannulated currently during any of a variety of percutaneous transvenous diagnostic and therapeutic procedures. Permanent placement of pacemaker and defibrillator leads within the coronary sinus and veins is both safe and well tolerated.

The annuloplasty system consists of several components. There is a delivery system intended to be introduced percutaneously into a central vein such as the internal jugular, subclavian or femoral veins and to cannulate the coronary sinus. The implant of the present invention is deployed from the delivery catheter into the coronary venous system. Additional tools may be placed through or along the delivery catheter to position the device, apply elements in place, and to control and/or cut the tensioning elements from the delivery system as will be discussed.

Referring to FIG. **1**, there is illustrated a schematic view of the heart **10**, having a mitral annuloplasty and cardiac reinforcement device **40** positioned therein. The heart **10** generally comprises a right atrium **12**, in communication with the superior vena cava **14** and inferior vena cava **16**. The left ventricle **18** is positioned below the left atrial appendage **20**. Relevant portions of the coronary vasculature include the coronary sinus **22**, which extends from the ostium **24** to the junction **26** of the coronary sinus and the great cardiac vein **28**. There may be anastomotic connections **29** between the great cardiac vein **28** and the middle cardiac vein **30**, as is well understood in the art.

One embodiment of a mitral annuloplasty and cardiac reinforcement device **40** in accordance with the present invention is illustrated generally in the coronary sinus **22**. In particular, the device **40** extends from a proximal end **42** to a distal end **44**. The proximal end **42** lies against the posterior aspect of the interatrial septum **46**. The midportion **48** of the device **40** is positioned within the coronary sinus **22**. The transitional section **50** of the device **40** lies at the junction **26** of the coronary sinus **22** and the great cardiac vein **28**. The distal end **44** of the device **40** is lodged in the great cardiac vein **28**.

The transitional region **50** is designed to reside in the proximal portion of the great cardiac vein **28**. By deflecting out of the plane of the coronary sinus **22**, it serves as an anchor **52** and prevents the device **40** from slipping out of the coronary sinus **22** when tension is applied. This embodiment of an anchor **52** is very flaccid and flexible, thereby minimizing the risk of erosion of the device **40** through the wall of the great cardiac vein or other aspect of the coronary

venous system. The proximal end **42** of the device **40** lies outside the ostium **24** of the coronary sinus **22** and is curved upward so as to anchor against the posterior aspect of the interatrial septum **46**. The proximal end **42** is semicircular in shape and elliptical in profile so that no edges will promote erosion of adjacent tissue.

As an alternative anchor **52** to the distal extension of the device **40**, any of a variety of structures may be provided. In general, the deployed device **40** will contact the wall of the coronary sinus **22** along the inside radius of its arcuate path. Thus, a tissue contacting surface **54** on the concave side of the deployed device **40** may be provided with any of a variety of friction enhancing surface structures, such as a plurality of transverse ridges, teeth or other projections, or modified surface textures to enhance friction. Alternatively, tissue engaging or piercing structures such as barbs may be provided on the surface **54** to engage the wall of the coronary sinus **22** to resist movement of the device **40**.

While use of such structures as anchors may provide some benefit in certain applications, embodiments herein shown and described are believed to be particularly useful in one aspect specifically because they operate without the need for such aggressive tissue engagement. It is apparent to one of ordinary skill based upon this disclosure that the present embodiments provide independent device manipulation and shape control that allow for sufficient forces to be applied to the mitral valve without requiring the possibly harmful effects of puncturing and grabbing tissue within the sinus for the remodeling process. In one regard, the independent action of a barbless design allows for adjustment in both the tightening and loosening directions with reduced risk of significant tissue damage or erosion. In another regard, the present device according at least to certain embodiments beneficially maintains its length throughout its modified range of shapes while the sinus and adjacent valve annulus reduce their dimensions under the force of remodeling. In still a further regard, the independent action and lack of tissue piercing and grabbing anchors allow for the device to be removed from the patient after initial implantation within the sinus, such as for example in the event of complications or in applications intended to be temporary remedial measures, such as for bridging a patient. Further to this regard, various shapes and sizes of devices may be required in a given patient before the appropriate one is found according to the observed in vivo response to implantation.

The specific dimensions, construction details and materials for the mitral annuloplasty and cardiac reinforcement device **40** can be varied widely, as will be appreciated by those of skill in the art in view of the disclosure herein. For example, dimensional adjustments may be made to accommodate different anatomical sizes and configurations. Materials and construction details can be varied to accommodate different tensioning mechanisms and other considerations.

In general, the device **40** has an overall length from proximal end **42** to distal end **44** within the range of from about 2 cm to about 10 cm, in an embodiment such as that illustrated in FIG. **2** in which the anchor **52** comprises a distal extension of the body **66** for lodging within the great cardiac vein **28**. One embodiment of the device **40** includes an elongate flexible body **66** about eight centimeters in length. In this embodiment, the body **66** is preferably elliptical in cross section so that it will bend in the plane of the coronary sinus **22** and mitral annulus when force is applied to the tensioning element within it (discussed below). Distally the device tapers and transitions to a round cross-section.

Referring to FIG. **2**, there is illustrated an embodiment of the device **40** having a forming element **56** therein. Manipulation of the forming element **56** allows the device to be moved from a flexible orientation to enable percutaneous insertion into the vascular system and navigation into the coronary sinus, to an arcuate configuration for compressing at least a portion of the mitral annulus. The device **40** may be advanced from the first, flexible configuration to the second, arcuate configuration by either axial proximal retraction or distal advancement of the forming element **56** with respect to the body **66**, depending upon the particular design.

In general, the device **40** comprises an elongate flexible support **58**, extending from a proximal end **42** at least as far as a point of attachment **60**. The support **58** may be a portion of the body **66** or may be a distinct component as will be discussed. The support **58** has a fixed length, and is relatively axially noncompressible or expandable. Thus, proximal retraction of the forming element **56** compared to the proximal end of the support **58** will cause the support **58** to deflect in a first direction. Distal axial advancement of the forming element **56** with respect to the support **58** will cause lateral deflection of the support **58** in a second direction. This basic steering configuration can be embodied in many forms, which can be optimized by those of skill in the art to suit a particular construction for the body **66** depending upon the desired dimensions and clinical performance.

The forming element **56** extends from the proximal end **42** through the device **40** to the point of attachment **60**. At the point of attachment **60**, the forming element **56** is mechanically linked, and preferably, directly linked to the support **58**. A proximal extension **64** of the forming element **56** extends from the proximal end **42** of the device **40**, such as through an aperture **62**. Proximal retraction of the forming element **56** through the aperture **62** causes the device **40** to bend from an implantation orientation for navigating the coronary vasculature during implantation to a formed orientation for compression and constraint of the coronary sinus **22** and adjacent structures.

In the formed orientation, the device **40** preferably provides a compressive force against the mitral annulus as has been discussed. This is accomplished by forming the device into an arcuate configuration. Generally, the best fit curve of constant radius to which the formed device conforms has a radius within the range of from about 1.0 cm to about 2.0 cm.

The forming element may comprise any of a variety of components, such as a polymeric or metal wire or strand, a multifillament braided or woven line, a metal or polymeric ribbon, or other structure capable of retaining the device **40** under tension in the coronary sinus **22**.

The device **40** further comprises a support **58**, which may be the body **66** of the device **40** or a separate element positioned therein. In an embodiment in which the support **58** is a separate element contained within the device **40**, support **58** may comprise any of a variety of generally axially non-compressible elements such as a metal or polymeric wire or column, ribbon, or "bottomed out" spring which facilitates lateral bending but inhibits axial compression upon proximal retraction of forming element **56**. A metal ribbon comprising stainless steel, nitinol, or other known materials may be desired in certain embodiments, due to its ability to influence the plane of curvature of the device **40** when in the formed orientation.

The proximal extension **64** of the forming element **56** extends proximally throughout the length of the deployment catheter, to a control or free end which remains outside of the patient during the deployment procedure. Following

placement of the device **40** in the coronary sinus, proximal traction on the proximal extension **64** will reconfigure the device **40** into the formed orientation within the coronary sinus, as will be discussed in connection with the method of the present invention. After a sufficient tension has been placed on the coronary sinus, the forming element **56** is preferably axially locked to the device **40**, to resist distal movement of the forming element **56** through aperture **62**. Any of a variety of locks **70** may be provided. Preferably, the lock **70** is provided on or near the proximal end **42**, and, in particular, at or about the aperture **62**. The lock may comprise any of a variety of structures, such as a suture knot, locking clamp or ring, an interference fit, ratchet and pall structures, an adhesive bond, or a compression fit, as will be apparent to those of skill in the art in view of the disclosure herein.

The lock **70** (on any of the embodiments herein) may be initially disengaged, so that the forming element **56** may be retracted or advanced freely through the aperture **62** while the physician adjusts the tension on the device **40**. After the desired tension is achieved, the lock **70** is activated to engage the forming element in a manner which will depend upon the lock design. Alternatively, the lock **70** may be biased into an engaged configuration, such as with ratchet or cam structures, so that the forming element can only be retracted proximally. Preferably, however, the lock will allow the forming element to be released so that the physician can release tension in the device **40** in the event of momentary over tightening.

Referring to FIGS. **7–9**, there is disclosed one embodiment of a releasable lock **70** in accordance with the present invention. Although the lock **70** is illustrated as a discrete component of the system, it can alternatively be formed integrally with or attached to the proximal end of the body **66**. The lock **70** comprises a body **114**, which may be in the form of an annular collar with a central aperture for axial movement over the forming element **56**. The body **114** is provided with one or two or three or more releasable locking elements **126** which ramp radially inwardly in the proximal direction.

Each locking element **126** is provided with at least one engagement surface **122** for engaging the forming element **56**. The forming element **56** may be provided with any of a variety of friction enhancing surface textures or structures to enhance the locking function. Thus, a locking zone along the forming element may be provided with an etched surface or friction enhancing coating. Alternatively, structures such as a plurality of beads or teeth can be provided to permit an interference fit with the engagement surface **122**.

The engagement surface **122** is movable between a first, disengaged configuration and a second, engaged configuration. This may be accomplished by pivoting the locking element **126** about a fulcrum **118**. In the illustrated embodiment, fulcrum **118** is formed by an annular ring **119**. Alternatively, the fulcrum **118** can be formed by plastic deformation of an integral structure, such as a living hinge formed by one or more annular grooves in the body **114**.

The locking elements **126** may be biased in the locked direction, unlocked direction, or neutrally. Locking may be accomplished by pressing distally on a locking surface **124** such as with a locking tool **125** (FIG. **8**) which applies distal pressure on the ramped locking element **126** at a point which is displaced radially inwardly from the fulcrum **118**. Unlocking may be accomplished by distally advancing an unlocking tool **128** against a release surface **120** which is displaced radially outwardly from the fulcrum **118**. In one embodiment, the locking tool **125** and unlocking tool **128** are conveniently formed from concentric tubular elements as will be apparent to those of skill in the art. The tubular elements or proximally extending control wires extend proximally to controls outside of the patient. Alternatively, any of a variety of ramped engagement surfaces and tools can be readily configured to accomplish the lock and/or release functions in view of the disclosure herein.

The length of the device **40** from proximal end **42** through the point of attachment **60** is generally within the range of from about 2 cm to about 10 cm, and, preferably within the range of from about 6 cm to about 8 cm. The shape of the device **40** is preferably designed to minimize trauma to the vascular intima, both during implantation and following placement. This may be accomplished by rounding all edges which may come into contact with the vessel wall. Thus, the cross-section through the mid portion **48** of the device, for example, may be elliptical, semicircular or otherwise rounded, or rectangular with rounded corners. In general, the maximum area of a cross-section of the device **40** will be no more than about 15 mm^2, and preferably no more than about 10 mm^2, for implantation within a human adult.

The device **40** may be manufactured in accordance with any of a variety of techniques, which will be apparent to those of skill in the art in view of the disclosure herein. For example, the body **66** may be formed by extrusion, injection molding, or other techniques. In one embodiment, the forming element **56** is secured at point of attachment **60** to an elongate flexible support **58** and coextruded within a polymeric body **66**. Alternatively, the forming element **56** and support **58** subassembly may be positioned within a mold cavity, and injection molded to produce the final device **40**. The body **66** may comprise any of a variety of biocompatible materials such as various densities of polyethylenes, nylon, polyethylene terephthalate, PEBAX, and others which will be apparent to those of skill in the art.

Alternatively, the forming element **56** and support **58** may be surrounded by a tubular jacket of ePTFE or Dacron fabric, or other material which is wrapped or stitched onto the forming element **56** to produce the final device **40**. As a further alternative, the subassembly which includes the forming element **56** and, if present, support **58** may be positioned within a suitable length of tubing formed such as by extrusion. The tubing may be drawn down to a reduced diameter at the distal end **44**. Additional post extrusion steps may be used to produce the desired cross-sectional configuration. Manufacturing techniques for the present invention will be apparent to those of skill in the art in view of the disclosure herein.

Any of a variety of additional features may be added to the device **40**, depending upon the desired clinical performance. For example, the outside surface of the body **66** may be provided with any of a variety of coatings, such as Paralene, PTFE or others to improve lubricity; heparin or other antithrombogenic agents; elastomers such as silicone, neoprene, latex or others to soften the surface and reduce the risk of trauma to the vascular intima, and the like. Adhesion enhancing surfaces may be provided, such as ePTFE patches or jackets, to promote cellular ingrowth for long term anchoring. In addition, depending upon the deployment system design, the body **66** may be provided with a guidewire lumen extending axially therethrough, to allow the body **66** to be advanced distally over a guidewire during placement at the treatment site.

The device **40** may be implanted within the coronary sinus **22** either through direct surgical (e.g. thoracotomy

with or without sternotomy) access, such as in combination with another surgical procedure, via port access, or remotely by way of a percutaneous or surgical cut down access to the venous system. Preferably, the device **40** is implanted in a transluminal procedure, such as by way of a percutaneous access at one of the internal jugular, subclavian, or femoral veins.

Referring to FIG. **3**, there is disclosed a deployment system **72** for deploying the device **40** of the present invention. The deployment system **72** comprises an introducer sheath or catheter **74** for percutaneous venous access procedures. In some circumstances, however, the system **72** includes a first introducer sheath **74** for simply gaining percutaneous access into the vasculature at a remote location from the heart, and a slideably engageable second introducer sheath or guiding catheter is deliverable through such a percutaneous introducer sheath. Introducer sheath **74** has an elongate flexible tubular body **76** extending from a proximal end **78** to a distal end **80**. A preset curve **82** is provided near the distal end **80** of the tubular body **76**, as is known in the cardiac access catheter arts. At least one lumen **84** extends through the tubular body **76**. In one embodiment, the lumen **84** has a noncircular cross section, such as an ellipse having the major axis perpendicular to the plane of curvature of the introducer sheath **74**.

Introducer sheaths are well known in the art, and may be manufactured such as by extrusion, with or without a braided reinforcement structure in the wall. The length and diameter of the introducer sheath **74** may vary considerably, depending upon the dimensions of the device **40** as well as the access point for percutaneous access into the vascular system. For a femoral vein access, for example, the introducer sheath may have a length within the range of from about 80 cm to about 120 cm. Preferably, the outside diameter of the introducer sheath **74** is no more than about 10 French (approximately 3.3 mm).

A pusher or dilator **86** as shown provides specific embodiments for a broader aspect that is a delivery member used in an overall assembly for delivering, i.e. advancing or pushing, the device prosthesis into the coronary sinus in a translumenal procedure, as is apparent to one of ordinary skill based upon the figures and accompanying disclosure herein. Delivery member or dilator **86** has an axial length of from about 10 cm to about 20 cm greater than the axial length of the introducer sheath **74**. Dilator **86** has an outside diameter which is less than the inside diameter of the lumen **84**, so that the dilator **86** may be freely axially advanced through the lumen **84**. The dilator **86** is provided with a central lumen **88**, for axially moveably receiving the proximal extension **64** of forming element **56**.

When assembled for deployment of a device **40** within the coronary vasculature, a device **40** is positioned within a distal portion of the lumen **84**. The dilator **86** is positioned proximal to the device **40** within the lumen **84**, and the proximal extension **64** of forming element **56** extends proximally through central lumen **88** of dilator **86**. During proximal movement of the introducer sheath **74** with respect to the dilator **86**, a distal surface **90** on dilator **86** resists proximal movement of the device **40**. Thus, the device **40** may be deployed from the distal end **80** of introducer sheath **74**. In addition, proximal retraction of the proximal extension **64** while proximal movement of the device **40** is prevented by surface **90** causes the device **40** to advance from its deployment configuration to its implanted configuration.

Once the coronary sinus **22** has been cannulated by the introducer sheath **74**, the dilator that is loaded over the forming element is advanced through the sheath **74**. This is used to push the device **40** to the proper location with the distal tip **44** in the distal portion of the great cardiac vein **28**. Using counter traction of the forming element and the dilator, the device is curved until the appropriate degree of annular remodeling has been achieved. A locking ring **70** on the forming element that is interposed between the dilator and the device prevents the forming element from slipping distally once the device **40** has been curved. A locking ring **70** that can be released by using a dilator with a different tip geometry may also be employed. After satisfactory deployment and deflection of the device **40**, the forming element **56** is cut with a cutting tool (not illustrated) that is placed through the introducer sheath.

A second embodiment of the device does not contain an axially moveable forming element. Instead, a core of springy memory material such as nitinol or other NiTi alloy is pre-formed to have the required configuration. When the device is pushed out of the delivery catheter into the coronary venous system, the spring force within the core applies the requisite force to remodel the annulus. This embodiment does not require a tensioning element or a tool to disconnect it from the delivery system. However, the magnitude of force applied to the annulus cannot be adjusted.

A third embodiment is deployed as a loop through the coronary venous system, to form a left ventricular girdle **100**. See FIGS. **5–6**. The ventricular girdle **100** comprises an elongate flexible body **102** having a proximal end **104** and a distal end **106**. A first control line **108** extends proximally from the proximal end **104**, and a second control line **110** extends distally from distal end **106**. The first and second control lines **108** and **110** may be different portions of the same wire, which extends continuously throughout the length of the body **102**. The wire may be a single strand or multi strand component, a length of hypodermic needle tubing, a spring coil, or other structure known in the medical guidewire arts. Preferably, the first and second control lines have a diameter within the range of from about 0.009" to about 0.018", although larger diameters may also be used particularly for the first control line **108**.

The distal control line **110** is advanced through an introducer sheath into the great cardiac vein **28** and then through anastomotic connections **29** into the middle cardiac vein **30**. Continued advancement results in the tip of the distal control line **110** emerging from the ostium **24** of the coronary sinus **22**. The control line **110** is then harnessed with a snare and pulled retrogradely through the delivery catheter as illustrated in FIG. **5**. The body **102** is then pulled into the coronary venous system. The body is preferably larger in diameter than the first and second control lines **108** and **110**, and preferably elliptical or otherwise noncircular in cross section. This shape enlarges the transverse tissue contact surface area and reduces the risk of erosion when tension is applied to the loop. Both the proximal and distal ends of the loop are threaded through a locking clip **112**. A dilator is used to push the clip **112** through the delivery catheter to the level of the coronary sinus ostium. Using counter traction on the dilator and the first and second control lines **108** and **110**, the clip **112** is cinched on the loop until the requisite degree of tension is produced. Finally, the device is separated from the delivery system using a cutting tool to cut the first and second control lines **108** and **110**, and possibly proximal and distal ends **104** and **106** to the extent they extend proximally from clip **112**.

The overall length of the embodiment illustrated in FIG. **5** should be sufficient that both of the first control line **108**

and second control line **110** can extend outside of the patient, while the body **102** extends throughout the pathway of the ventricular girdle **100** as illustrated in FIG. **6**. For a percutaneous femoral vein access, the overall length of the device is therefore preferably at least about 200 cm, and generally within the range of from about 220 cm to about 260 cm. The length of the body **102** from proximal end **104** to distal end **106** is preferably sufficient to form a closed loop as illustrated in FIG. **6**. Although both heart size and the shape of the vascular pathway will vary from individual to individual, the length of the body **102** is generally within the range of from about 6 cm to about 12 cm. The body **102** may be injection molded, extruded as a tube, or coextruded over the wire which forms first and second control lines **108** and **110**. Preferably the body **102** either comprises or is coated with a material which is sufficiently compliant to minimize trauma to the vascular intima. Also, the transverse width of a tissue contacting surface **113** on body **102** is preferably sufficient to distribute compressive force to minimize the risks of localized pressure necrosis within the coronary veins.

FIGS. **10–13B** variously show another particular device assembly **200** that includes various aspects that are believed to be readily adapted for use according to various of the embodiments of the present invention as introduced above.

In general, FIG. **10** shows an overall view of assembly **200** that includes a delivery assembly **210** which is engaged to a prosthesis **250**. According to similar overall delivery systems and methods elsewhere herein described, prosthesis **250** is adapted to be delivered in a first condition and shape into a vessel at least in part by manipulation of delivery assembly **210**. Once in the desired region of the target vessel, prosthesis **250** is adapted to be adjusted to a second condition and shape within the vessel in order to influence an adjacent tissue structure. As also elsewhere herein described, a particularly beneficial mode of such operation places the prosthesis **250** within a coronary sinus for the purpose of influencing a mitral valve annulus, more specifically in order to influence the shape of the annulus in order to reduce mitral valve regurgitation.

FIGS. **11A–B** show the proximal aspects of device assembly **200**, and in particular various details for delivery assembly **210** that includes an outer member **215** that is generally tubular with an inner lumen **216** that is sized to house an inner member **225**. Inner member **225** in the variation shown is generally tubular and is substantially free to rotate within lumen **216** by providing rotational force to inner member **225** proximally outside of the patient's body. According to the example shown, this rotational force is applied to inner member **225** via a thumbwheel **205** that is provided on proximal hub assembly **201** that is coupled to proximal end portion **211** of delivery assembly **210**. Thumbwheel **205** is rotationally coupled to inner member **225** within hub assembly **201**, which rotational coupling may be achieved according to a number of adaptions as would be apparent to one of ordinary skill.

Rotation of inner member **225** is transmitted into rotation of a rotational coupler **280** that is engaged within a proximal end portion **252** of prosthesis **250** as follows. Inner member **225** has an aperture **228** on its distal end portion that provides a female counterpart of a mated key interface between the inner member **225** and a male counterpart provided by a shaped proximal end **281** of a rotational coupler **280** that is also rotationally engaged within a proximal end portion **252** of prosthesis **250**. The keyed fitting between inner member **225** and rotational coupler **280** allows for transmission of rotational forces to rotational coupler **280**. In order to maintain releasable axial engagement of this keyed coupling, a flexible member such as a filament **240** is looped through an aperture **283** through proximal end **281** of rotational coupler **280** with both filament ends **242** and **244** extending proximally through inner member **225** to a location in proximal coupler. This filament **240** is generally held in sufficient tension to keep the distal keyed fitting engaged, though it is further contemplated that the mere presence of the filament may provide an interference against uncoupling if there is a sufficiently tight tolerance in the male/female interface of the keyed fitting.

Rotational coupler **280** is rotationally engaged within proximal end portion **252** of prosthesis **250** through proximal port or aperture **251** such that rotational coupler **280** is adapted to rotate within and relative to the prosthesis. This relative rotation is converted to force a deflection of prosthesis **250** into the desired shape of the second configuration in situ as follows.

According to one aspect of the rotational coupling, the prosthesis **250** is preferably held to resist rotation while rotation coupler **280** is rotated within the prosthesis **250**. This may be achieved simply by frictional forces of surrounding tissue as prosthesis **250** is delivered into the desired vessel such as the coronary sinus. According to another example, this may be achieved by providing a releasable interface **218** such as a friction fit between outer member **215** and proximal end portion **252** of prosthesis **250**, wherein the frictional engagement of outer member **215** and prosthesis **250** are held in a relatively fixed position while inter member **225** and rotational coupler **280** are rotated. This embodiment is shown in FIG. **11A**. In addition or in the alternative to the friction fit interface, a keyed interface may be employed as shown in FIGS. **12A–B**. According to this mode, a shaped proximal fitting **253** on the proximal end **252** of prosthesis **250** is adapted to mate as a male counterpart into a shaped aperture or fitting on the distal end **212** of outer member **215**. This keyed interface allows for rotational coupling between the members in a similar manner as just described for the inner member **225** and rotational coupler **280**, and may allow for a more releasable coupling with reduced friction upon axial detachment of the members.

According to another aspect, the rotational forces from rotational coupler may be converted to deflection forces on the prosthesis **250** according to one example as illustrated in the specific illustrative embodiment of FIGS. **10–13B**, and in particular detail in FIGS. **13A–B**. Prosthesis **250** includes a generally tubular wall or body **260** that has an inner lumen **262** and extends from the proximal end portion **252** to the distal end portion **254** of prosthesis **250**. Secured along proximal end portion **252** is a nut fitting **263** that has a grooved inner bore **264** which communicates with inner lumen **262**. Further to this specific embodiment, rotational coupler **280** is a screw member with outer groove or grooves **285** engaged within the mating grooved inner surface (not shown) of a bore lumen **264** such that a distal end of screw member **285** extends distally within lumen **262** and terminates at a second key fitting **287** similar to the shaped proximal end portion **282** and also having an aperture **288**. Similar to the proximal end of rotational coupler **280**, another flexible member or filament **290** is looped through aperture **288** such that two arms **292,294** extend distally therefrom to an attachment point along distal end portion **254** of prosthesis **250**. Because nut fitting **263** is fixed in relation to outer tubular body **260**, and because that tubular body is held relatively fixed position as provided above,

rotation of rotational coupler **280** moves coupler **280** proximally relative to body **260**. This proximal axial translation of rotational coupler pulls tension on filament **290**, which pulls tension on the body **260** due to the distal attachment. This tension on outer body **260** forces a deflection of that body. Therefore, rotational forces are translated into tensile forces which are translated into radial deflection forces relative to the longitudinal axis L of the device.

The forced deflection just described may be controlled in a particular plane by providing a composite structure within prosthesis **250** that is engineered to respond, i.e. yield, to these forces in a prescribed way. In the specific desirable embodiment shown, a relatively rigid spine member **270** is provided within lumen **262** of outer tubular body **260**. This spine member **270** is more rigid and more resistant to axial forces than the material of outer tubular body **260** alone, and therefore providing spine member **270** along only one radial aspect of the prosthesis **250** creates a bias on the device to deflect away from that spine toward a more compressive region of the device. Such composite design may further include a laminant structure, imbedded wire reinforced wall structure, or may be achieved by engineering material variations in the device, such as for example by thinning, thickening, hardening, or softening the material at one location along the outer tubular body **260** relative to another region to force deflection at a desired location.

As may be achieved by other controllable embodiments elsewhere herein described, deflection according to the present embodiment may be adjusted according to a healthcare provider's desires, and is adjustable in either direction—by either tightening the radius of curvature R or opening it. According to this specific embodiment however, the adjustability of and choice between tightening and loosening of the deflection depends upon the direction and extent of rotation placed upon the rotational force transmission system.

In any event, once the desired deflection is achieved and desired therapeutic results are observed, the prosthesis **250** may be detached from the delivery assembly **210** by severing the torque or rotational force transmission system at the keyed fitting between the inner member **225** and the rotational coupler **280**. This is accomplished by first releasing at least one arm **242,244** of the proximal filament **240** while withdrawing the other arm, thereby threading the filament **240** through aperture **283** (as shown in bold arrows in FIG. **13B**) until it is unthreaded completely from the aperture **283**. This allows inner member **225** to be withdrawn proximally from rotational coupler **280** to detach therefrom and thereby implant prosthesis **250**. Alternatively, as with other adjustable deflection systems herein described, the prosthesis may be held in its therapeutic condition for a temporary period of time (which may nevertheless be prolonged during a hospital stay), during which time mitral valve regurgitation may be minimized, such as for example for the purpose of bridging the patient in a temporarily improved condition until other treatments may be performed, e.g. annuloplasty, valve surgery, heart transplant, etc. In this alternative temporary setting, at the appropriate time the deflected, contracted prosthesis may be adjusted back open from its cinched position around the valve, and then withdrawn without implantation by withdrawing the entire system, delivery assembly still engaged to the prosthesis. Moreover, it is further contemplated that such a temporary prosthesis may be modified to remove the detachment mechanisms herein described, which may provide for a simpler and lower cost device.

Device assembly **200** is also shown in various of the FIGS. **10–13B** to include a distal guidewire tracking member with a guidewire lumen **265** which is adapted to slideably engage a guidewire **230** in order to be placed in a percutaneous translumenal procedure into the desired vessel location, such as within the coronary sinus. The particular guidewire lumen shown is integral within the distal aspects of prosthesis **250** as a "rapid exchange" or "monorail" design that allows for relatively independent movement of the guidewire and catheter in vivo. Moreover, this design removes the need for the guidewire to ride coaxial through the entire device assembly **200**, as would be the case for example in an "over the wire" type system. The type shown beneficially allows for detachable engagement of prosthesis **250**, which is preferably achieved after withdrawing the guidewire from the distal lumen **265**.

In each of the foregoing implantation methods, the physician preferably monitors the degree of regurgitation during the step of tightening the implant. Although any reduction in mitral regurgitation may be desirable, regurgitation is preferably reduced to something less than moderate (less than 2+). In any event, at least a one grade reduction is preferably achieved. On the other hand, reconfiguration of the implant should not be accomplished to an extent sufficient to produce mitral stenosis, or any flow limitation of hemodynamic significance.

Thus, the method of implantation preferably further comprises the steps of monitoring the degree of mitral regurgitation during the implantation and/or reconfiguration steps. The degree of mitral regurgitation may be monitored such as by transesophageal echo cardiography, surface echo cardiography, intracardiac echo cardiography, fluoroscopy using radiocontrast in the left ventricle (LVgram), or left atrial or pulmonary capillary wedge pressure tracings, as are understood in the art, during the incremental restriction of the mitral annulus and/or left ventricle step. Once a sufficient reduction in regurgitation has been achieved for a particular patient in the physician's judgement, the device is locked and the proximal extension of the forming element is severed from the device and removed from the patient.

The method may additionally comprise the step of measuring the coronary sinus and/or other coronary vein, and selecting an appropriately sized implant from an array of implants of varying sizes. Such parameters may include diameter, length, or radius of curvature of the arc of the sinus. The appropriately sized implant is thereafter positioned within the target vein. The implant is thus preferably provided in a graduated array of sizes, so that the optimal size can be selected for each patient. The size of the coronary sinus or other vein can be measured using any of a variety of techniques, such as echo cardiogram, MRI, CT scan, or angiography as is understood in the art. Moreover, as is apparent to one of ordinary skill, measuring a parameter of the coronary sinus generally provides indicia of certain parameters of the mitral valve and its annulus, such as for example mitral valve diameter, in which case either the coronary sinus parameter or the mitral valve parameter may provide the requisite information for choosing an appropriately dimensioned device from the kit. It follows that such mitral valve parameters may further be measured directly, such as by various of the methods just described, in order to generate the values used for choosing the appropriate device. Once a parameter for an anatomical feature is measured as herein described, its value is generally estimated according to the accuracy of the respective measuring tool—it is contemplated that persons without specialized medical skills or training can choose the appropriate medical device from the kit once armed with this estimated value. For example, packaging for each device of the kit may indicate the

respective dimensions that are unique to that device with respect to other devices of the kit, and the estimated value of the measured anatomical parameter may simply be compared.

It is contemplated and apparent that various of the embodiments herein described are adapted to accomplish device manipulation within the coronary sinus for mitral annulus reduction without substantially altering the length of the device within the sinus. This may provide a benefit by increasing the useful purchase of the device along the coronary sinus and circumferentially around the mitral annulus as the sinus length and/or annulus diameter may be reduced during remodeling from the radial deflection of the prosthetic device. This may also mean that the dimension of the device in a kit of devices may not directly correspond to the estimated value of the anatomical parameter that is measured. For example, the compared value of the measured device parameter may be shorter than an estimated coronary sinus length due to a possible shortening of the sinus during device treatment. Or, the anatomical parameter may be estimated from an initial value based upon an anticipated or desired final result from treatment and such procedurally related value be used for choosing the appropriate device (e.g. comparing an estimated final length of the sinus or mitral valve diameter with a known dimension of the device in the remodeling configuration when used in situ).

As a further aspect to the present invention, the implant is preferably combined with an appropriate drug therapy for treating congestive heart failure. Residual regurgitation and other hemodynamic functions are preferably measured following implantation of the implant of the present invention. Heart medications are preferably adjusted to take into account the reduction in regurgitation and/or reduction in left ventricle volume in formulating an ongoing drug therapy for the patient.

Still further, the aspect of the present invention that allows for temporary use in the sinus for mitral valve remodeling as a bridging regime in combination with other permanent treatments such as more conventional annuloplasty or valve replacement via surgery. Such combined systems of devices and respective methods of use, which may further be combined with the pharmaceutical drug regimes, provide an overall treatment regime that provides a highly beneficial result for management of patients with harmful mitral valve regurgitation.

In accordance with further aspect of the present invention, there is provided a method of constricting the left ventricle. Left ventricular constriction may be desirable in patients without mitral regurgitation. One implementation of this method comprises implanting the ventricular girdle **100** as illustrated, for example, in FIGS. **5** through **6** and previously discussed herein.

Any of the embodiments disclosed herein may additionally be provided with one or more externally facing electrically conductive axially extending strips or annular bands, to enable the device **40** to function additionally as a cardiac pacing or other cardiac electrode. The electrically conductive band or bands are placed in electrical communication with a pacing source or diagnostic instrument by way of one or more electrical conductors extending away from the device **40**. The conductors may be electrically connected to any of a wide variety of electronic cardiac rhythm management devices, which are well known in the art.

Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments or performed through other steps by persons of skill in the art in view of the disclosure herein. The scope of the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

What is claimed is:

1. An implant for positioning within a vessel to influence tissue outside of the vessel, comprising:

an elongate, flexible body, having a proximal end and a distal end, each of the proximal and distal ends dimensioned to reside completely within the vascular system; and

a forming element attached within the body, the forming element comprising a polymeric strand;

wherein rotation of at least a portion of the forming element with respect to the body changes the shape of the body from an implantation configuration to a remodeling configuration, wherein at least a portion of the forming element remains attached to the body following implantation.

2. An implant as in claim **1**, wherein the body is reversibly movable between an implantation configuration for transluminal implantation and a remodeling configuration for exerting a force against a vessel wall.

3. An implant as in claim **2**, wherein the body defines an arc when in the remodeling configuration.

4. An implant as in claim **3**, wherein a best fit constant radius curve corresponding to the arc has a radius within the range of from about 10 mm to about 20 mm.

5. An implant as in claim **1**, further comprising a lock for retaining the body in the remodeling configuration.

6. An implant as in claim **5**, wherein the lock comprises a locking ring.

7. An implant as in claim **5**, wherein the lock comprises an interference fit.

8. An implant as in claim **5**, wherein the lock comprises an adhesive bond.

9. An implant as in claim **5**, wherein the lock comprises a suture knot.

10. An implant as in claim **5**, wherein the lock comprises a clamp.

11. An implant as in claim **5**, wherein the lock comprises a compression fit.

12. An implant as in claim **5**, wherein the lock comprises a ratchet.

13. An implant as in claim **5**, wherein the lock comprises an engagement surface, which is movable between a first, disengaged configuration and a second, engaged configuration.

14. An implant as in claim **5**, wherein the lock is biased in a locked direction.

15. An implant as in claim **5**, wherein the lock is biased in an unlocked direction.

16. An implant as in claim **5**, further comprising a coating on the body.

17. An implant as in claim **1**, further comprising an anchor for retaining the implant at a deployment site within a vessel.

18. An implant as in claim **17**, wherein the anchor comprises a distal extension of the implant.

19. An implant as in claim **17**, wherein the anchor comprises a friction enhancing surface structure for engaging the wall of the vessel.

20. An implant as in claim **17**, wherein the anchor comprises at least one barb for piercing the wall of the vessel.

21. An implant as in claim **1**, wherein the body has an axial length of no more than about 10 cm.

22. An implant as in claim 1, wherein the maximum cross sectional dimension through the implant is no more than about 10 mm.

23. An implant as in claim 1, further comprising an axially extending support in the body, attached to the forming element.

24. An implant as in claim 1, wherein the forming element comprises a metal wire.

25. An implant as in claim 1, wherein the forming element comprises a multifilament structure.

26. An implant as in claim 1, wherein the forming element comprises a screw thread.

27. An implant for positioning within a vessel to influence tissue outside of the vessel, comprising:

an elongate, flexible body, having a proximal end and a distal end, each of the proximal and distal ends dimensioned to reside completely within the vascular system; and

a forming element attached within the body, the forming element comprising a screw, at least partially within the flexible body;

wherein rotation of at least a portion of the forming element with respect to the body changes the shape of the body from an implantation configuration to a remodeling configuration, wherein at least a portion of the forming element remains attached to the body following implantation.

28. An implant as in claim 27, wherein the body is reversibly movable between an implantation configuration for transluminal implantation and a remodeling configuration for exerting a force against a vessel wall.

29. An implant as in claim 28, wherein the body defines an arc when in the remodeling configuration.

30. An implant as in claim 29, wherein a best fit constant radius curve corresponding to the arc has a radius within the range of from about 10 mm to about 20 mm.

31. An implant as in claim 27, further comprising a lock for retaining the body in the remodeling configuration.

32. An implant as in claim 31, wherein the lock comprises a locking ring.

33. An implant as in claim 31, wherein the lock comprises an interference fit.

34. An implant as in claim 31, wherein the lock comprises an adhesive bond.

35. An implant as in claim 31, wherein the lock comprises a suture knot.

36. An implant as in claim 31, wherein the lock comprises a clamp.

37. An implant as in claim 31, wherein the lock comprises a compression fit.

38. An implant as in claim 31, wherein the lock comprises a ratchet.

39. An implant as in claim 31, wherein the lock comprises an engagement surface, which is movable between a first, disengaged configuration and a second, engaged configuration.

40. An implant as in claim 31, wherein the lock is biased in a locked direction.

41. An implant as in claim 31, wherein the lock is biased in an unlocked direction.

42. An implant as in claim 31, further comprising a coating on the body.

43. An implant as in claim 27, further comprising an anchor for retaining the implant at a deployment site within a vessel.

44. An implant as in claim 43, wherein the anchor comprises a distal extension of the implant.

45. An implant as in claim 43, wherein the anchor comprises a friction enhancing surface structure for engaging the wall of the vessel.

46. An implant as in claim 43, wherein the anchor comprises at least one barb for piercing the wall of the vessel.

47. An implant as in claim 27, wherein the body has an axial length of no more than about 10 cm.

48. An implant as in claim 27, wherein the maximum cross sectional dimension through the implant is no more than about 10 mm.

49. An implant as in claim 27, further comprising an axially extending support in the body, attached to the forming element.

50. An implant as in claim 27, wherein the forming element comprises a polymeric strand.

51. An implant as in claim 27, wherein the forming element comprises a multifilament structure.

52. An implant for positioning within a vessel to influence tissue outside of the vessel, comprising:

an elongate, flexible body, having a proximal end and a distal end, each of the proximal and distal ends dimensioned to reside completely within the vascular system; and

a forming element attached within the body, the forming element comprising a multifilament structure;

wherein rotation of at least a portion of the forming element with respect to the body changes the shape of the body from an implantation configuration to a remodeling configuration, wherein at least a portion of the forming element remains attached to the body following implantation.

53. An implant as in claim 52, wherein the body is reversibly movable between an implantation configuration for transluminal implantation and a remodeling configuration for exerting a force against a vessel wall.

54. An implant as in claim 53, wherein the body defines an arc when in the remodeling configuration.

55. An implant as in claim 54, wherein a best fit constant radius curve corresponding to the arc has a radius within the range of from about 10 mm to about 20 mm.

56. An implant as in claim 52, further comprising a lock for retaining the body in the remodeling configuration.

57. An implant as in claim 56, wherein the lock comprises a locking ring.

58. An implant as in claim 56, wherein the lock comprises an interference fit.

59. An implant as in claim 56, wherein the lock comprises an adhesive bond.

60. An implant as in claim 56, wherein the lock comprises a suture knot.

61. An implant as in claim 56, wherein the lock comprises a clamp.

62. An implant as in claim 56, wherein the lock comprises a compression fit.

63. An implant as in claim 56, wherein the lock comprises a ratchet.

64. An implant as in claim 56, wherein the lock comprises an engagement surface, which is movable between a first, disengaged configuration and a second, engaged configuration.

65. An implant as in claim 56, wherein the lock is biased in a locked direction.

66. An implant as in claim 56, wherein the lock is biased in an unlocked direction.

67. An implant as in claim 56, further comprising a coating on the body.

68. An implant as in claim 52, further comprising an anchor for retaining the implant at a deployment site within a vessel.

69. An implant as in claim 68, wherein the anchor comprises a distal extension of the implant.

70. An implant as in claim 68, wherein the anchor comprises a friction enhancing surface structure for engaging the wall of the vessel.

71. An implant as in claim 68, wherein the anchor comprises at least one barb for piercing the wall of the vessel.

72. An implant as in claim 52, wherein the body has an axial length of no more than about 10 cm.

73. An implant as in claim 52, wherein the maximum cross sectional dimension through the implant is no more than about 10 mm.

74. An implant as in claim 52, further comprising an axially extending support in the body, attached to the forming element.

75. An implant as in claim 52, wherein the forming element comprises a polymeric strand.

76. An implant as in claim 52, wherein the forming element comprises a metal wire.

77. An implant as in claim 52, wherein the forming element comprises a screw thread.

* * * * *

US006402781B1

(12) **United States Patent**
Langberg et al.

(10) **Patent No.: US 6,402,781 B1**
(45) **Date of Patent: Jun. 11, 2002**

(54) **PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT**

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(73) Assignee: **Mitralife**, Santa Rosa, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/494,233**

(22) Filed: **Jan. 31, 2000**

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(52) **U.S. Cl.** **623/2.36**; 623/2.37; 623/1.11
(58) **Field of Search** 623/1.1, 1.11–1.54, 623/2.1–2.42

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Primary Examiner—David J. Isabella
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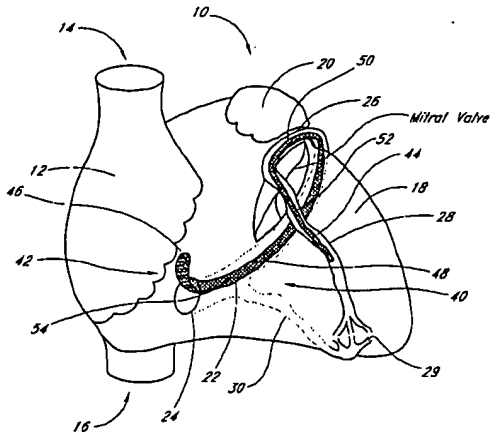
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A mitral annuloplasty and LV restriction device is designed to be transvenously advanced and deployed within the coronary sinus and in some embodiments other coronary veins. The device places tension on adjacent structures, reducing the diameter and/or limiting expansion of the mitral annulus and/or limiting diastolic expansion of the left ventricle. These effects may be beneficial for patients with dilated cardiomyopathy.

46 Claims, 10 Drawing Sheets



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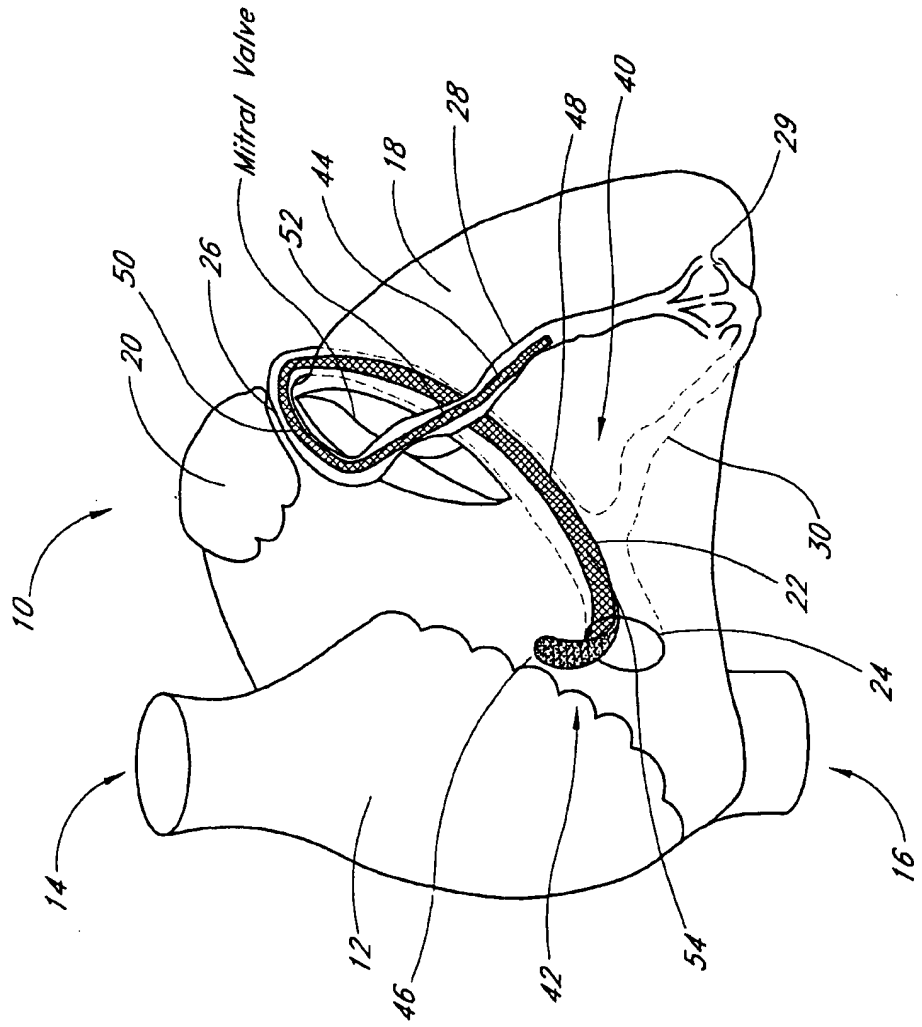
Mitral Valve
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FIG. 1

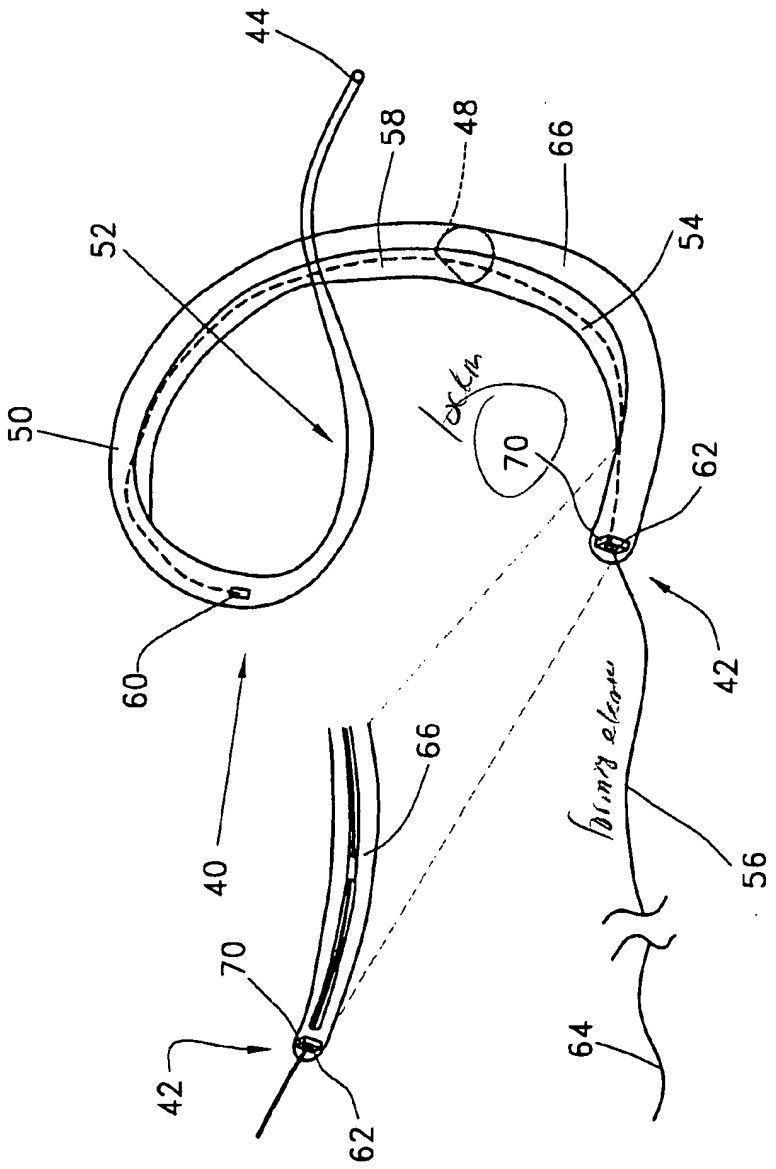

FIG. 2

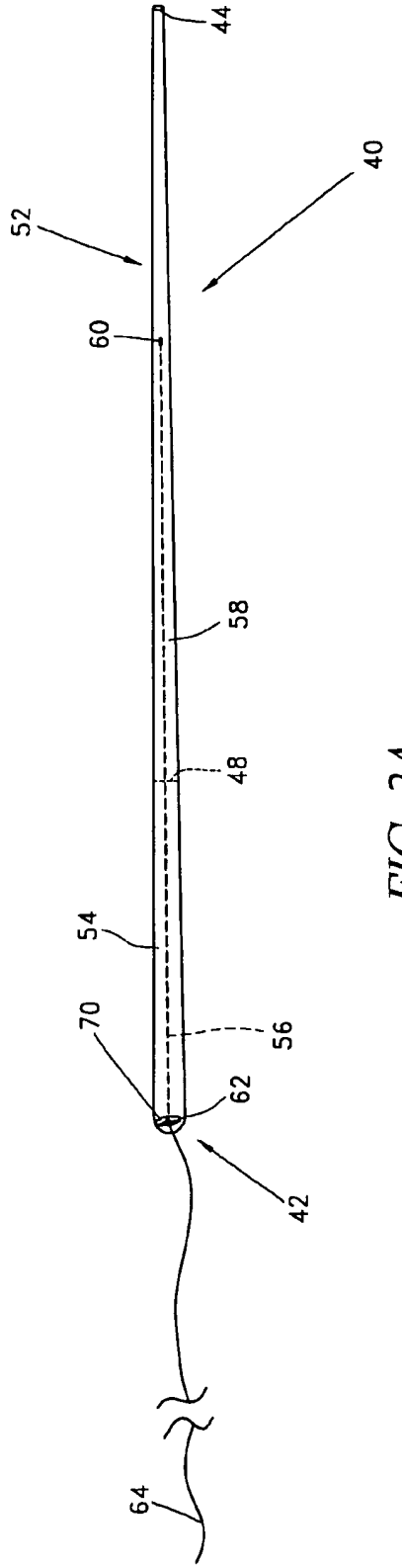

FIG. 2A

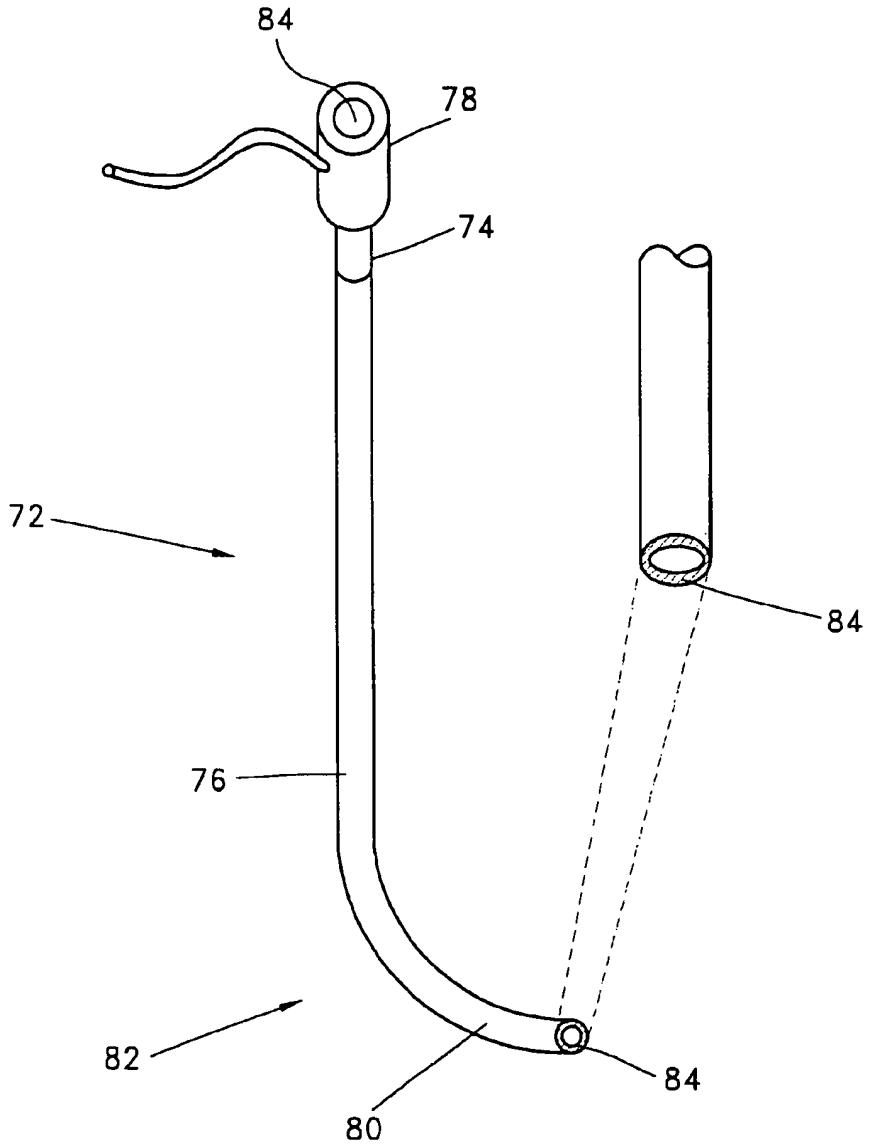

FIG. 3

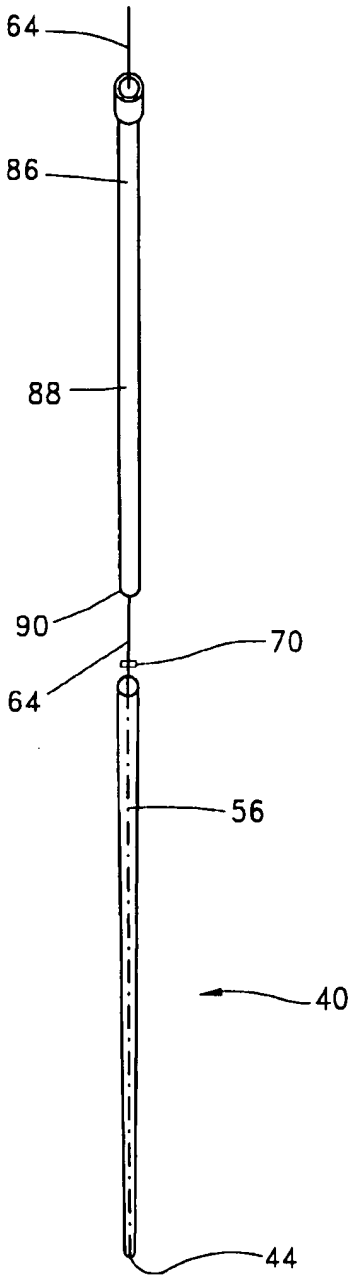

FIG. 4

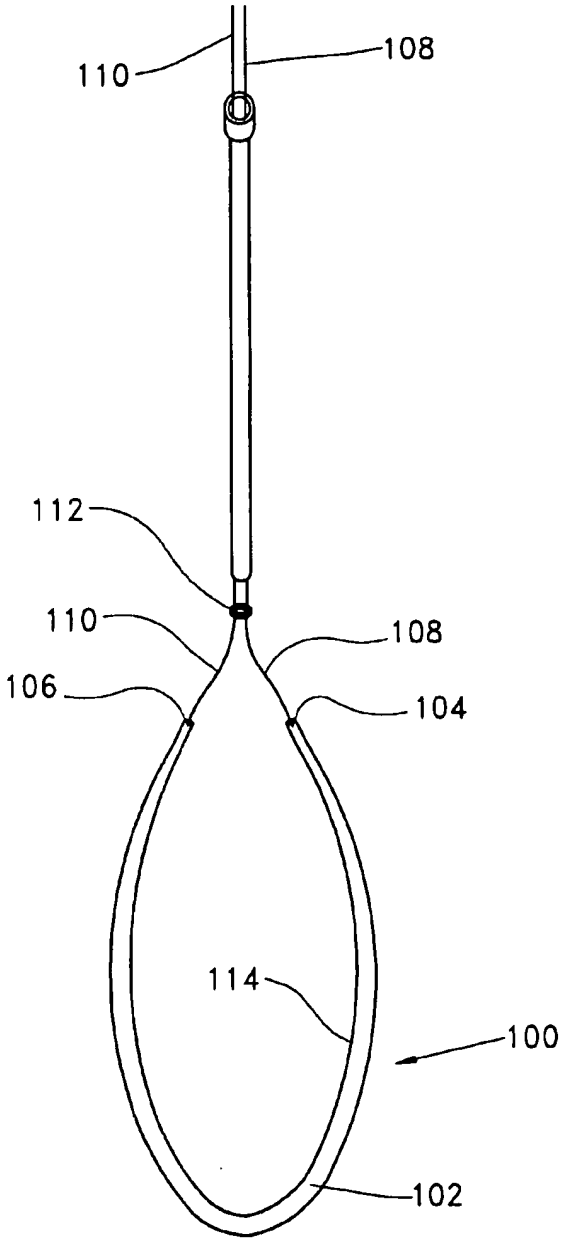

FIG. 5

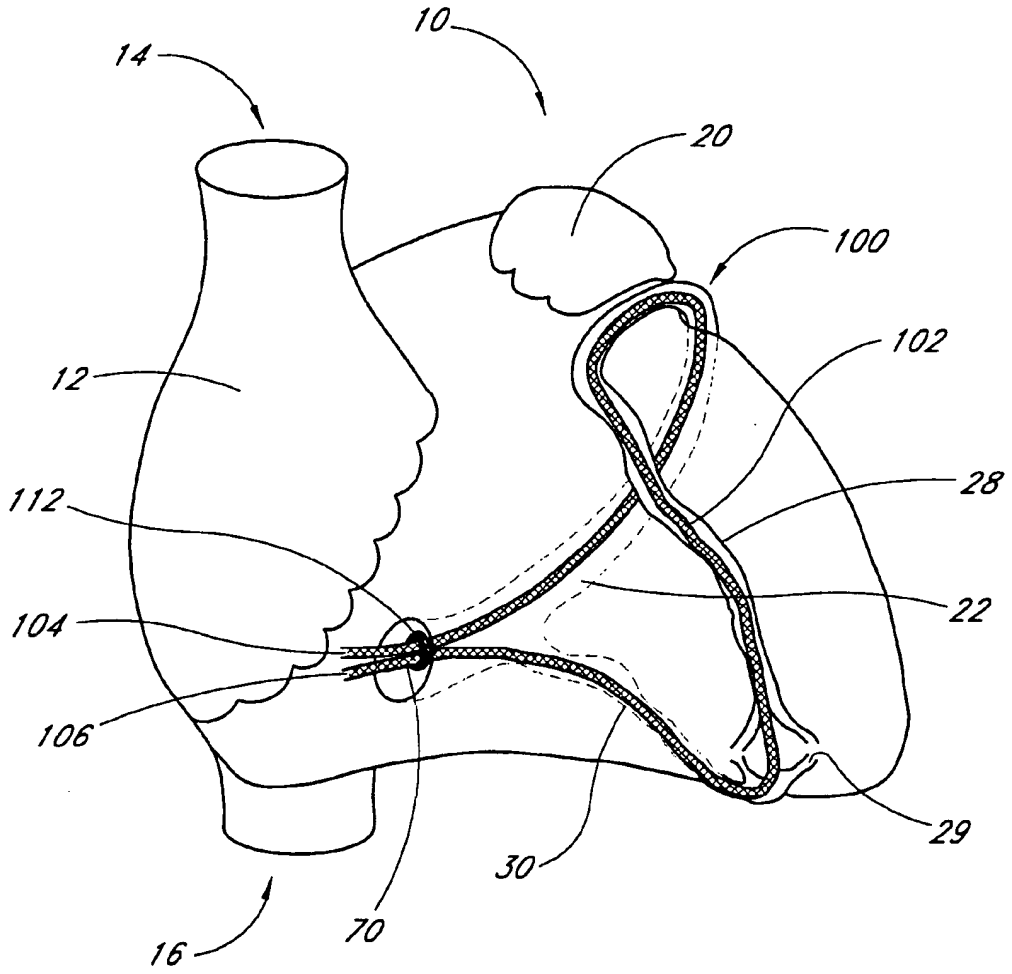

FIG. 6

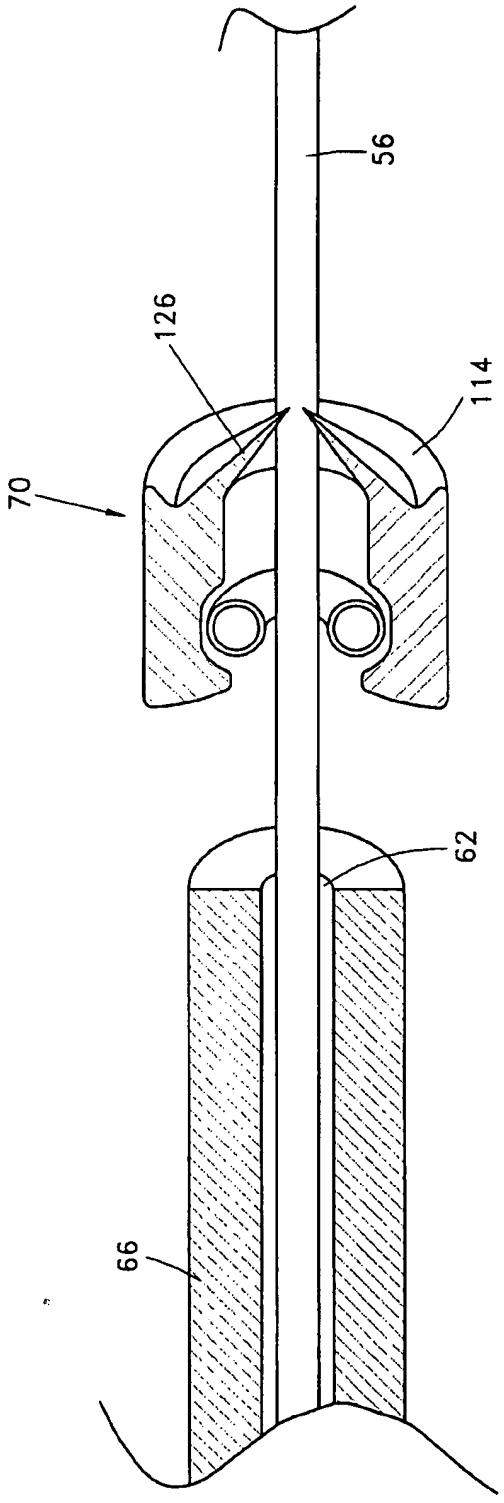

FIG. 7

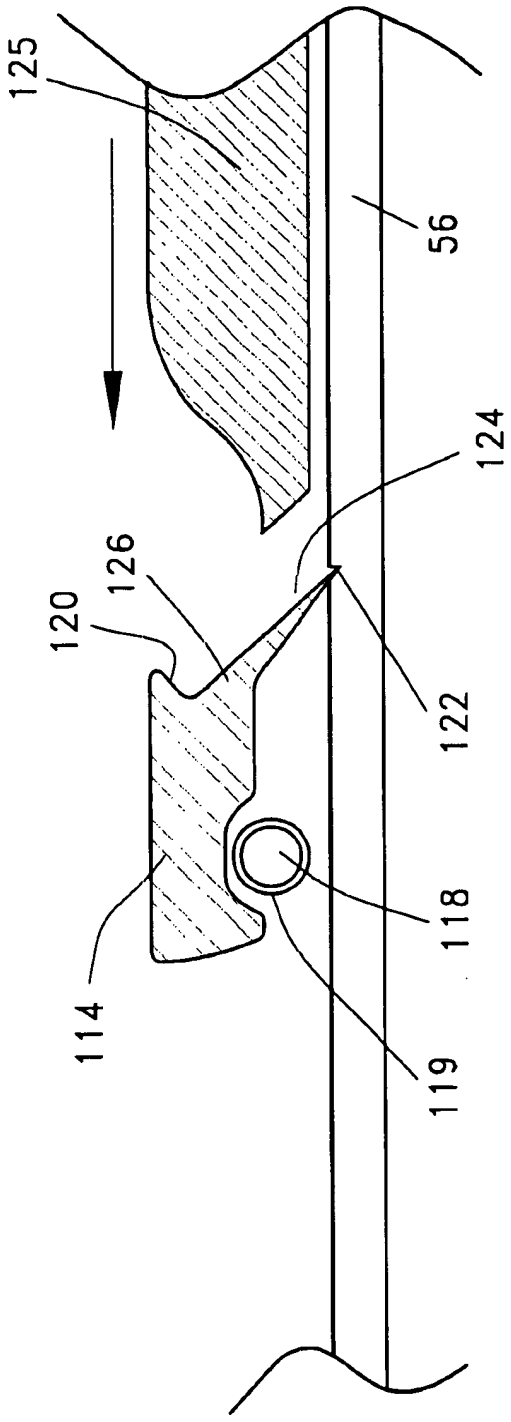

FIG. 8

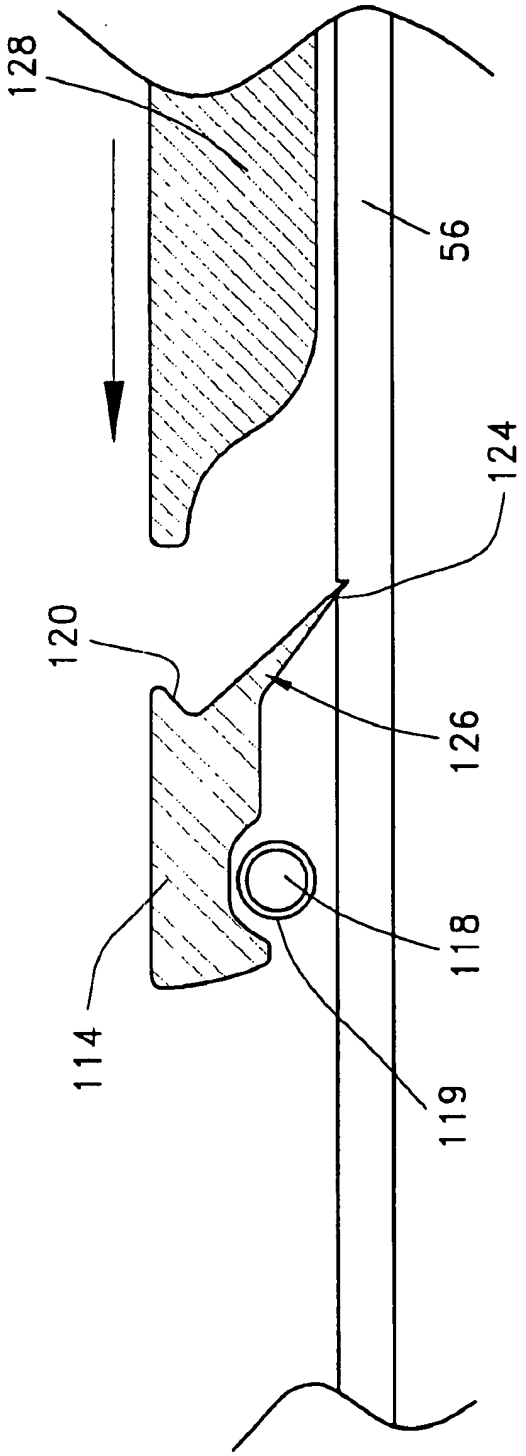

FIG. 9

PERCUTANEOUS MITRAL ANNULOPLASTY AND CARDIAC REINFORCEMENT

The present invention relates to intravascular prostheses for remodeling an extravascular anatomical structure. In one application, the present invention relates to a mitral annuloplasty and cardiac reinforcement device which is transluminally implantable in the coronary sinus.

BACKGROUND OF THE INVENTION

Dilated cardiomyopathy occurs as a consequence of many different disease processes that impair myocardial function, such as coronary artery disease and hypertension. The left ventricle enlarges and the ejection fraction is reduced. The resulting increase in pulmonary venous pressure and reduction in cardiac output cause congestive heart failure. Enlargement of the mitral annulus and left ventricular cavity produce mitral valvular insufficiency, This in turn, causes volume overload that exacerbates the myopathy, leading to a vicious cycle of progressive enlargement and worsening mitral regurgitation.

According to recent estimates, more than 79,000 patients are diagnosed with aortic and mitral valve disease in U.S. hospitals each year. More than 49,000 mitral valve or aortic valve replacement procedures are performed annually in the U.S., along with a significant number of heart valve repair procedures.

Various surgical techniques have been developed to repair a diseased or damaged valve. One repair technique which has been shown to be effective in treating incompetence, particularly of the mitral and tricuspid valves, is annuloplasty, in which the effective size of the valve annulus is contracted by attaching a prosthetic annuloplasty ring to the endocardial surface of the heart around the valve annulus. The annuloplasty ring comprises an inner substrate of a metal such as stainless steel or titanium, or a flexible material such as silicone rubber or Dacron cordage, covered with a biocompatible fabric or cloth to allow the ring to be sutured to the heart tissue. The annuloplasty ring may be stiff or flexible, may be split or continuous, and may have a variety of shapes, including circular, D-shaped, C-shaped, or kidney-shaped. Examples are seen in U.S. Pat. Nos. 4,917,698, 5,061,277, 5,290,300, 5,350,420, 5,104,407, 5,064,431, 5,201,880, and 5,041,130, which are incorporated herein by reference.

Annuloplasty rings may also be utilized in combination with other repair techniques such as resection, in which a portion of a valve leaflet is excised, the remaining portions of the leaflet are sewn back together, and a prosthetic annuloplasty ring is then attached to the valve annulus to maintain the contracted size of the valve. Other valve repair techniques in current use include commissurotomy (cutting the valve commissures to separate fused valve leaflets), shortening mitral or tricuspid valve chordae tendonae, reattachment of severed mitral or tricuspid valve chordae tendonae or papillary muscle tissue, and decalcification of the valve leaflets or annulus. Annuloplasty rings may be used in conjunction with any repair procedures where contracting or stabilizing the valve annulus might be desirable.

Although mitral valve repair and replacement can successfully treat many patients with mitral valvular insufficiency, techniques currently in use are attended by significant morbidity and mortality. Most valve repair and replacement procedures require a thoracotomy, usually in the form of a median sternotomy, to gain access into the patient's thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing the two opposing halves of the anterior or ventral portion of the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgical team may directly visualize and operate upon the heart and other thoracic contents. Alternatively, a thoracotomy may be performed on a lateral side of the chest, wherein a large incision is made generally parallel to the ribs, and the ribs are spread apart and/or removed in the region of the incision to create a large enough opening to facilitate the surgery.

Surgical intervention within the heart generally requires isolation of the heart and coronary blood vessels from the remainder of the arterial system, and arrest of cardiac function. Usually, the heart is isolated from the arterial system by introducing an external aortic cross-clamp through a sternotomy and applying it to the aorta to occlude the aortic lumen between the brachiocephalic artery and the coronary ostia. Cardioplegic fluid is then injected into the coronary arteries, either directly into the coronary ostia or through a puncture in the ascending aorta, to arrest cardiac function. The patient is placed on extracorporeal cardiopulmonary bypass to maintain peripheral circulation of oxygenated blood.

Of particular interest in the present application are techniques for the repair and replacement of the mitral valve. The mitral valve, located between the left atrium and left ventricle of the heart, is most easily reached through the wall of the left atrium, which normally resides on the posterior side of the heart, opposite the side of the heart that is exposed by a median stemotomy. Therefore, to access the mitral valve via a sternotomy, the heart is rotated to bring the left atrium into an anterior position. An opening, or atriotomy, is then made in the right side of the left atrium, anterior to the right pulmonary veins. The atriotomy is retracted by means of sutures or a retraction device, exposing the mitral valve adjacent to the atriotomy. One of the previously identified techniques may then be used to repair or replace the valve.

An alternative technique for mitral valve access has been used when a median sternotomy and/or rotational manipulation of the heart are inappropriate. In this technique, a thoracotomy is made in the right lateral side of the chest, usually in the region of the fourth or fifth intercostal space. One or more ribs may be removed from the patient, and other ribs near the incision are retracted outward to create a large opening into the thoracic cavity. The left atrium is then exposed on the posterior side of the heart, and an atriotomy is formed in the wall of the left atrium, through which the mitral valve may be accessed for repair or replacement.

Using such open-chest techniques, the large opening provided by a median stemotomy or right thoracotomy enables the surgeon to see the mitral valve directly through the left atriotomy, and to position his or her hands within the thoracic cavity in close proximity to the exterior of the heart for cannulation of the aorta and/or coronary arteries to induce cardioplegia, manipulation of surgical instruments, removal of excised tissue, and introduction of an annuloplasty ring or a replacement valve through the atriotomy for attachment within the heart.

Mitral valve surgery, including mitral annuloplasty, is usually applied to patients with intrinsic disease of the mitral apparatus. As described above, these patients may have scarring, retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. Definitive repair requires direct visualization of the valve.

Patients who develop mitral regurgitation as a result of dilated cardiomyopathy do not have intrinsic mitral valve

disease. Regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. The ventricle enlarges and becomes spherical, pulling the papillary muscles and chordae away from the plane of the valve and further enlarging the regurgitant orifice. In these patients, correction of the regurgitation does not require repair of the valve leaflets themselves, but simply a reduction in the size of the annulus and the sphericity of the left ventricle.

Mitral annuloplasty without repair of the leaflets or chordae has been shown to be effective in patients with dilated cardiomyopathy who are refractory to conventional medical therapy. Bolling and coworkers have operated on a cohort of such patients with New York Heart Association Class III and IV symptoms. Average symptom severity decreased from 3.9 preoperatively to 2.0 after surgery. Hemodynamics and ejection fraction improved significantly. Other investigators have achieved similar results as well. However, the morbidity, risks and expense of surgical annuloplasty are very high in patients with cardiomyopathy and congestive heart failure. Thus, a variety of new techniques for the treatment of congestive heart failure are being explored as adjuncts to drug therapy.

Several cardiac restraint devices have been described. U.S. Pat. No. 5,702,343 to Alferness discloses a cardiac reinforcement device that is applied as a jacket over the epicardium in order to limit diastolic expansion. However, this requires an open chest operation to implant and does not directly affect the diameter of the mitral annulus. Another approach is disclosed in U.S. Pat. No. 5,961,440 to Schweich, et al., in which tension members are placed through opposite walls of the heart such that they span the ventricle. Less invasive and "minimally" invasive techniques for valve repair and replacement continue to evolve, both on a stopped heart and on a beating hearts These techniques may provide some benefits over open chest procedures, but they are still attended by significant morbidity and mortality risks.

A need therefore remains for methods and devices for treating mitral valvular insufficiency, which are attended by significantly lower morbidity and mortality rates than are the current techniques, and therefore would be well suited to treat patients with dilated cardiomyopathy. Optimally, the procedure can be accomplished through a percutaneous, transluminal approach, using simple, implantable devices which do not depend upon prosthetic valve leaflets or other moving parts.

SUMMARY OF THE INVENTION

There is provided in accordance with one aspect of the present invention, a method of treating mitral valvular insufficiency. The method comprises the steps of transvenously advancing a prosthesis into the coronary sinus, and deploying at least a portion of the prosthesis within the coronary sinus to reduce the diameter of the mitral annulus. Although deployment can be accomplished in an open surgical procedure, the method preferably further comprises the step of percutaneously accessing the venous system prior to the transluminally advancing step. The venous system may be accessed by one of the internal jugular, subclavian, or femoral veins. Preferably, the deploying step further includes the step of advancing the prosthesis from a first configuration for transluminal implantation to a second configuration to apply pressure to the wall of the coronary sinus and thereby reduce and/or restrain the diameter of the mitral valve annulus.

In accordance with another aspect of the present invention, there is provided a method of performing transluminal mitral annuloplasty. The method comprises the steps of providing a catheter which carries a prosthesis, and percutaneously inserting the catheter into the venous system. The prosthesis is transluminally advanced into the coronary sinus, and deployed in the coronary sinus to influence the size of the mitral valve annulus. Preferably, the prosthesis is caused to exert a compressive force on the mitral valve annulus.

The compressive force of one embodiment is generated by a bias in the prosthesis. In an alternate embodiment, the compressive force is generated by tightening the prosthesis around the mitral valve annulus following the transluminally advancing step. The tightening step may be accomplished by axial movement of a tightening element with respect to the prosthesis.

In accordance with a further aspect of the present invention, there is provided a method of providing a therapeutic compressive force against a tissue structure which is distinct from a vessel wall. The method comprises the steps of positioning a device in the vessel, and exerting a force against the wall of the vessel to exert a force against an extravascular tissue structure. Preferably, the positioning step is accomplished percutaneously. In one application, the extravascular tissue structure comprises the mitral valve annulus. Thus, the present invention provides a method of performing annuloplasty of the mitral valve, comprising positioning a prosthesis in the venous sinus.

In accordance with another aspect of the present invention, there is provided an implant for extravascular remodeling, for positioning within a vascular structure to influence tissue outside of the vessel. The implant comprises an elongate flexible support, having a proximal end and a distal end. Each of the proximal and distal ends are dimensioned to reside completely within the vascular system. A forming element is attached to the support, such that movement of the forming element relative to the support changes the shape of the support. The support is thus moveable between an implantation configuration for transluminal implantation and a remodeling configuration for exerting a force against a vessel wall. In one application, the support defines an arc when in the remodeling configuration.

Preferably, the implant for extravascular remodeling further comprises a lock for restraining the support in the remodeling configuration. In one embodiment, the lock comprises a locking ring. Alternatively, the lock comprises a compression fit, an interference fit or an adhesive bond.

The support is moveable from the implantation configuration to the remodeling configuration in response to movement of a remodeling control such as proximal retraction of the forming element. Alternatively, the support is moveable from the implantation configuration to the remodeling configuration in response to distal advancement of the forming element.

In one embodiment, the implant for extravascular remodeling further comprises an anchor for retaining the implant at a deployment site within a vessel. In one application, the anchor comprises a distal extension of the support, for positioning within the great cardiac vein. Alternatively, the anchor comprises a friction enhancing surface texture or structure for engaging the wall of the vessel. In a further embodiment, the anchor comprises at least one barb for piercing the wall of the vessel.

In accordance with yet a further aspect of the present invention, there is provided a transluminally implantable

annuloplasty device. The annuloplasty device comprises a flexible body, having a proximal end and a distal end. An annuloplasty zone is provided on a proximal portion of the body, and an anchor zone is provided on a distal portion of the body. An axially moveable forming element is attached to the body between a mid-point of the annuloplasty zone and a mid-point of the anchor zone, such that proximal retraction of the forming element with respect to the proximal end of the body advances at least the annuloplasty zone into an arcuate configuration.

In accordance with a further aspect of the present invention, there is provided a method of treating a mitral valve. The method comprises the steps of providing an elongate flexible vascular implant, having a first attachment site spaced axially apart from a second attachment site. The first attachment site is transluminally advanced through the coronary sinus and coronary venous system to form the implant into an open loop. The open loop is reduced in size to place tension on the coronary sinus, and the first attachment site is attached to the second attachment site to close the loop and retain tension on the coronary sinus.

In accordance with another aspect of the present invention, there is provided a method of treating the heart. The method comprises the steps of advancing an implant through an access site and into a coronary vein such as the coronary sinus. A forming element on the implant is thereafter proximally retracted while resisting proximal movement of the implant, thereby forming the implant into a desired shape. The access site is thereafter closed, leaving the formed implant within the coronary vein.

Preferably, the method further comprises the step of locking the implant into the desired shape prior to the closing step. The method may additionally comprise the step of severing at least a portion of the forming element prior to the closing step.

Further features and advantages of the present invention will become apparent to those of ordinary skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of the heart, showing one embodiment of the mitral annuloplasty device of the present invention deployed within the coronary venous system.

FIG. **2** is a schematic illustration of the mitral annuloplasty device shown in FIG. **1**.

FIG. **2A** is a schematic illustration of the mitral annuloplasty device shown in FIG. **2**, in a linear configuration.

FIG. **3** is an overall view and cross-sectional view through a transvenous delivery sheath.

FIG. **4** is a schematic illustration of the delivery sheath and two different embodiments of the implant for extravascular remodeling, one with a forming element and one without.

FIG. **5** is a schematic illustration of an alternative embodiment of the present invention positioned in an open-loop configuration through the delivery sheath.

FIG. **6** is a schematic illustration of a heart, having an alternate embodiment of the mitral annuloplasty and cardiac reinforcement device of the present invention positioned within the coronary sinus and contiguous venous system.

FIG. **7** is a schematic cross-sectional view of one embodiment of a locking device in accordance with the present invention.

FIG. **8** is a fragmentary view of a portion of the lock illustrated in FIG. **7**, with a locking tool.

FIG. **9** is a fragmentary view as in FIG. **8**, showing an unlocking tool.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present invention provides a method and apparatus for performing mitral annuloplasty and remodeling of the left ventricle using a device that may be introduced percutaneously, and placed within the coronary venous system of the heart. The device exerts compressive force on the mitral annulus and left ventricle, reducing the severity of mitral regurgitation and the size of the left ventricular cavity. The device thus enables reduction of the mitral annulus and constraint of the diastolic expansion of the left ventricle yet without the morbidity and other risks associated with open chest surgery.

The present inventors have determined that the coronary sinus and veins provide an ideal conduit for the positioning of an intravascular prosthesis for remodeling the mitral annulus, since they are positioned adjacent the mitral annulus and interventricular septum. The cpronary sinus is contained within the atrioventricular groove, and is in close proximity to the posterior, lateral and anterior aspects of the mitral annulus. The coronary sinus and coronary veins are cannulated currently during any of a variety of percutaneous transvenous diagnostic and therapeutic procedures. Permanent placement of pacemaker and defibrillator leads within the coronary sinus and veins is both safe and well tolerated.

The annuloplasty system consists of several components. There is a delivery system intended to be introduced percutaneously into a central vein such as the internal jugular, subdlavian or femoral veins and to cannulate the coronary sinus. The implant of the present invention is deployed from the delivery catheter into the coronary venous system. Additional tools may be placed through or along the delivery catheter to position the device, apply elements in place, and to control and/or cut the tensioning elements from the delivery system as will be discussed.

Referring to FIG. **1**, there is illustrated a schematic view of the heart **10**, having a mitral annuloplasty and cardiac reinforcement device **40** positioned therein. The heart **10** generally comprises a right atrium **12**, in communication with the superior vena cava **14** and inferior vena cava **16**. The left ventricle **18** is positioned below the left atrial appendage **20**. Relevant portions of the coronary vasculature include the coronary sinus **22**, which extends from the ostium **24** to the junction **26** of the coronary sinus and the great cardiac vein **28**. There may be anastomotic connections **29** between the great cardiac vein **28** and the middle cardiac vein **30**, as is well understood in the art.

One embodiment of a mitral annuloplasty and cardiac reinforcement device **40** in accordance with the present invention is illustrated generally in the coronary sinus **22**. In particular, the device **40** extends from a proximal end **42** to a distal end **44**. The proximal end **42** lies against the posterior aspect of the interatrial septum **46**. The midportion **48** of the device **40** is positioned within the coronary sinus **22**. The transitional section **50** of the device **40** lies at the junction **26** of the coronary sinus **22** and the great cardiac vein **28**. The distal end **44** of the device **40** is lodged in the great cardiac vein **28**.

The transitional region **50** is designed to reside in the proximal portion of the great cardiac vein **28**. By deflecting out of the plane of the coronary sinus **22**, it serves as an

anchor **52** and prevents the device **40** from slipping out of the coronary sinus **22** when tension is applied. This embodiment of an anchor **52** is very flaccid and flexible, thereby minimizing the risk of erosion of the device **40** through the wall of the great cardiac vein or other aspect of the coronary venous system. The proximal end **42** of the device **40** lies outside the ostium **24** of the coronary sinus **22** and is curved upward so as to anchor against the posterior aspect of the interatrial septum **46**. The proximal end **42** is semicircular in shape and elliptical in profile so that no edges will promote erosion of adjacent tissue.

As an alternative anchor **52** to the distal extension of the device **40**, any of a variety of structures may be provided. In general, the deployed device **40** will contact the wall of the coronary sinus **22** along the inside radius of its arcuate path. Thus, a tissue contacting surface **54** on the concave side of the deployed device **40** may be provided with any of a variety of friction enhancing surface structures, such as a plurality of transverse ridges, teeth or other projections, or modified surface textures to enhance friction. Alternatively, tissue engaging or piercing structures such as barbs may be provided on the surface **54** to engage the wall of the coronary sinus **22** to resist movement of the device **40**.

The specific dimensions, construction details and materials for the mitral annuloplasty and cardiac reinforcement device **40** can be varied widely, as will be appreciated by those of skill in the art in view of the disclosure herein. For example, dimensional adjustments may be made to accommodate different anatomical sizes and configurations. Materials and construction details can be varied to accommodate different tensioning mechanisms and other considerations.

In general, the device **40** has an overall length from proximal end **42** to distal end **44** within the range of from about 2 cm to about 10 cm, in an embodiment such as that illustrated in FIG. **2** in which the anchor **52** comprises a distal extension of the body **66** for lodging within the great cardiac vein **28**. One embodiment of the device **40** includes an elongate flexible body **66** about eight centimeters in length. In this embodiment, the body **66** is preferably elliptical in cross section so that it will bend in the plane of the coronary sinus **22** and mitral annulus when force is applied to the tensioning element within it (discussed below). Distally the device tapers and transitions to a round cross-section.

Referring to FIG. **2**, there is illustrated an embodiment of the device **40** having a forming element **56** therein. Manipulation of the forming element **56** allows the device to be moved from a flexible orientation to enable percutaneous insertion into the vascular system and navigation into the coronary sinus, to an arcuate configuration for compressing at least a portion of the mitral annulus. The device **40** may be advanced from the first, flexible configuration to the second, arcuate configuration by either axial proximal retraction or distal advancement of the forming element **56** with respect to the body **66**, depending upon the particular design.

In general, the device **40** comprises an elongate flexible support **58**, extending from a proximal end **42** at least as far as a point of attachment **60**. The support **58** may be a portion of the body **66** or may be a distinct component as will be discussed. The support **58** has a fixed length, and is relatively axially non compressible or expandable. Thus, proximal retraction of the forming element **56** compared to the proximal end of the support **58** will cause the support **58** to deflect in a first direction. Distal axial advancement of the forming element **56** with respect to the support **58** will cause lateral deflection of the support **58** in a second direction. This basic steering configuration can be embodied in many forms, which can be optimized by those of skill in the art to suit a particular construction for the body **66** depending upon the desired dimensions and clinical performance.

The forming element **56** extends from the proximal end **42** through the device **40** to the point of attachment **60**. At the point of attachment **60**, the forming element **56** is mechanically linked, and preferably, directly linked to the support **58**. A proximal extension **64** of the forming element **56** extends from the proximal end **42** of the device **40**, such as through an aperture **62**. Proximal retraction of the forming element **56** through the aperture **62** causes the device **40** to bend from an implantation orientation for navigating the coronary vasculature during implantation to a formed orientation for compression and constraint of the coronary sinus **22** and adjacent structures.

In the formed orientation, the device **40** preferably provides a compressive force against the mitral annulus as has been discussed. This is accomplished by forming the device into an arcuate configuration. Generally, the best fit curve of constant radius to which the formed device conforms has a radius within the range of from about 1.0 cm to about 2.0 cm.

The forming element may comprise any of a variety of components, such as a polymeric or metal wire or strand, a multifillament braided or woven line, a metal or polymeric ribbon, or other structure capable of retaining the device **40** under tension in the coronary sinus **22**.

The device **40** further comprises a support **58**, which may be the body **66** of the device **40** or a separate element positioned therein. In an embodiment in which the support **58** is a separate element contained within the device **40**, support **58** may comprise any of a variety of generally axially non-compressible elements such as a metal or polymeric wire or column, ribbon, or "bottomed out" spring which facilitates lateral bending but inhibits axial compression upon proximal retraction of forming element **56**. A metal ribbon comprising stainless steel, nitinol, or other known materials may be desired in certain embodiments, due to its ability to influence the plane of curvature of the device **40** when in the formed orientation.

The proximal extension **64** of the forming element **56** extends proximally throughout the length of the deployment catheter, to a control or free end which remains outside of the patient during the deployment procedure. Following placement of the device **40** in the coronary sinus, proximal traction on the proximal extension **64** will reconfigure the device **40** into the formed orientation within the coronary sinus, as will be discussed in connection with the method of the present invention. After a sufficient tension has been placed on the coronary sinus, the forming element **56** is preferably axially locked to the device **40**, to resist distal movement of the forming element **56** through aperture **62**. Any of a variety of locks **70** may be provided. Preferably, the lock **70** is provided on or near the proximal end **42**, and, in particular, at or about the aperture **62** (FIG. **7**). The lock may comprise any of a variety of structures, such as a suture knot, locking clamp or ring, an interference fit, ratchet and pall structures, an adhesive bond, or a compression fit, as will be apparent to those of skill in the art in view of the disclosure herein.

locks

The lock **70** (on any of the embodiments herein) may be initially disengaged, so that the forming element **56** may be retracted or advanced freely through the aperture **62** while the physician adjusts the tension on the device **40**. After the

desired tension is achieved, the lock **70** is activated to engage the forming element in a manner which will depend upon the lock design. Alternatively, the lock **70** may be biased into an engaged configuration, such as with ratchet or cam structures, so that the forming element can only be retracted proximally. Preferably, however, the lock will allow the forming element to be released so that the physician can release tension in the device **40** in the event of momentary over tightening.

Referring to FIGS. **7–9**, there is disclosed one embodiment of a releasable lock **70** in accordance with the present invention. Although the lock **70** is illustrated as a discrete component of the system, it can alternatively be formed integrally with or attached to the proximal end of the body **66**. The lock **70** comprises a body **114**, which may be in the form of an annular collar with a central aperture for axial movement over the forming element **56**. The body **114** is provided with one or two or three or more releasable locking elements **126** which ramp radially inwardly in the proximal direction.

Each locking element **126** is provided with at least one engagement surface **122** for engaging the forming element **56**. The forming element **56** may be provided with any of a variety of friction enhancing surface textures or structures to enhance the locking function. Thus, a locking zone along the forming element may be provided with an etched surface or friction enhancing coating. Alternatively, structures such as a plurality of beads or teeth can be provided to permit an interference fit with the engagement surface **122**.

The engagement surface **122** is movable between a first, disengaged configuration and a second, engaged configuration. This may be accomplished by pivoting the locking element **126** about a fulcrum **118**. In the illustrated embodiment, fulcrum **118** is formed by an annular ring **119**. Alternatively, the fulcrum **118** can be formed by plastic deformation of an integral structure, such as a living hinge formed by one or more annular grooves in the body **114**.

The locking elements **126** may be biased in the locked direction, unlocked direction, or neutrally. Locking may be accomplished by pressing distally on a locking surface **124** such as with a locking tool **125** (FIG. **8**) which applies distal pressure on the ramped locking element **126** at a point which is displaced radially inwardly from the fulcrum **118**. Unlocking may be accomplished by distally advancing an unlocking tool **128** against a release surface **120** which is displaced radially outwardly from the fulcrum **118**. In one embodiment, the locking tool **125** and unlocking tool **128** are conveniently formed from concentric tubular elements as will be apparent to those of skill in the art. The tubular elements or proximally extending control wires extend proximally to controls outside of the patient. Alternatively, any of a variety of ramped engagement surfaces and tools can be readily configured to accomplish the lock and/or release functions in view of the disclosure herein.

The length of the device **40** from proximal end **42** through the point of attachment **60** is generally within the range of from about 2 cm to about 10 cm, and, preferably within the range of from about 6 cm to about 8 cm. The shape of the device **40** is preferably designed to minimize trauma to the vascular intima, both during implantation and following placement. This may be accomplished by rounding all edges which may come into contact with the vessel wall. Thus, the cross-section through the mid portion **48** of the device, for example, may be elliptical, semicircular or otherwise rounded, or rectangular with rounded corners. In general, the maximum cross-section of the device **40** will be no more than about 15 mm^2, and preferably no more than about 10 mm^2, for implantation within a human adult.

The device **40** may be manufactured in accordance with any of a variety of techniques, which will be apparent to those of skill in the art in view of the disclosure herein. For example, the body **66** may be formed by extrusion, injection molding, or other techniques. In one embodiment, the forming element **56** is secured at point of attachment **60** to an elongate flexible support **58** and coextruded within a polymeric body **66**. Alternatively, the forming element **56** and support **58** subassembly may be positioned within a mold cavity, and injection molded to produce the final device **40**. The body **66** may comprise any of a variety of biocompatible materials such as various densities of polyethylenes, nylon, polyethylene terepbthalate, PEBAX, and others which will be apparent to those of skill in the art.

Alternatively, the forming element **56** and support **58** may be surrounded by a tubular jacket of ePTFE or Dacron fabric, or other material which is wrapped or stitched onto the forming element **56** to produce the final device **40**. As a further alternative, the subassembly which includes the forming element **56** and, if present, support **58** may be positioned within a suitable length of tubing formed such as by extrusion. The tubing may be drawn down to a reduced diameter at the distal end **44**. Additional post extrusion steps may be used to produce the desired cross-sectional configuration. Manufacturing techniques for the present invention will be apparent to those of skill in the art in view of the disclosure herein.

Any of a variety of additional features may be added to the device **40**, depending upon the desired clinical performance. For example, the outside surface of the body **66** may be provided with any of a variety of coatings, such as Paralene, PTFE or others to improve lubricity; heparin or other antithrombogenic agents; elastomers such as silicone, neoprene, latex or others to soften the surface and reduce the risk of trauma to the vascular intima, and the like. Adhesion enhancing surfaces may be provided, such as ePTFE patches or jackets, to promote cellular ingrowth for long term anchoring. In addition, depending upon the deployment system design, the body **66** may be provided with a guidewire lumen extending axially therethrough, to allow the body **66** to be advanced distally over a guidewire during placement at the treatment site.

The device **40** may be implanted within the coronary sinus **22** either through direct surgical (e.g. thoracotomy with or without sternotomy) access, such as in combination with another surgical procedure, via port access, or remotely by way of a percutaneous or surgical cut down access to the venous system. Preferably, the device **40** is implanted in a transluminal procedure, such as by way of a percutaneous access at one of the internal jugular, subdlavian, or femoral veins.

Referring to FIG. **3**, there is disclosed a deployment system **72** for deploying the device **40** of the present invention. The deployment system **72** comprises an introducer sheath or catheter **74**, having an elongate flexible tubular body **76** extending from a proximal end **78** to a distal end **80**. A preset curve **82** is provided near the distal end **80** of the tubular body **76**, as is known in the cardiac access catheter arts. At least one lumen **84** extends through the tubular body **76**. In one embodiment, the lumen **84** has a noncircular cross section, such as an ellipse having the major axis perpendicular to the plane of curvature of the introducer sheath **74**.

Introducer sheaths are well known in the art, and may be manufactured such as by extrusion, with or without a

braided reinforcement structure in the wall. The length and diameter of the introducer sheath **74** may vary considerably, depending upon the dimensions of the device **40** as well as the access point for percutaneous access into the vascular system. For a femoral vein access, for example, the introducer sheath may have a length within the range of from about 80 cm to about 120 cm. Preferably, the outside diameter of the introducer sheath **74** is no more than about 10 French (approximately 3.3 m).

A pusher or dilator **86** has an axial length of from about **10** cm to about **20** cm greater than the axial length of the introducer sheath **74**. Dilator **86** has an outside diameter which is less than the inside diameter of the lumen **84**, so that the dilator **86** may be freely axially advanced through the lumen **84**. The dilator **86** is provided with a central lumen **88**, for axially moveably receiving the proximal extension **64** of forming element **56**.

When assembled for deployment of a device **40** within the coronary vasculature, a device **40** is positioned within a distal portion of the lumen **84**. The dilator **86** is positioned proximal to the device **40** within the lumen **84**, and the proximal extension **64** of forming element **56** extends proximally through central lumen **88** of dilator **86**. During proximal movement of the introducer sheath **74** with respect to the dilator **86**, a distal surface **90** on dilator **86** resists proximal movement of the device **40**. Thus, the device **40** may be deployed from the distal end **80** of introducer sheath **74**. In addition, proximal retraction of the proximal extension **64** while proximal movement of the device **40** is prevented by surface **90** causes the device **40** to advance from its deployment configuration to its implanted configuration.

Once the coronary sinus **22** has been cannulated by the introducer sheath **74**, the dilator that is loaded over the forming element is advanced through the sheath **74**. This is used to push the device **40** to the proper location with the distal tip **44** in the distal portion of the great cardiac vein **28**. Using counter traction of the forming element and the dilator, the device is curved until the appropriate degree of annular remodeling has been achieved. A locking ring **70** on the forming element that is interposed between the dilator and the device prevents the forming element from slipping distally once the device **40** has been curved. A locking ring **70** that can be released by using a dilator with a different tip geometry may also be employed. After satisfactory deployment and deflection of the device **40**, the forming element **56** is cut with a cutting tool (not illustrated) that is placed through the introducer sheath.

A second embodiment of the device is comparable to that described above except that it does not contain an axially moveable forming element. Instead, a core of springy memory material such as nitinol or other NiTi alloy is pre-formed to have the required configuration. When the device is pushed out of the delivery catheter into the coronary venous system, the spring force within the core applies the requisite force to remodel the annulus. This embodiment does not require a tensioning element or a tool to disconnect it from the delivery system. However, the magnitude of force applied to the annulus cannot be adjusted.

A third embodiment is deployed as a loop through the coronary venous system, to form a left ventricular girdle **100**. See FIGS. **5–6**. The ventricular girdle **100** comprises an elongate flexible body **102** having a proximal end **104** and a distal end **106**. A first control line **108** extends proximally from the proximal end **104**, and a second control line **110** extends distally from distal end **106**. The first and second control lines **108** and **110** may be different portions of the same wire, which extends continuously throughout the length of the body **102**. The wire may be a single strand or multi strand component, a length of hypodermic needle tubing, a spring coil, or other structure known in the medical guidewire arts. Preferably, the first and second control lines have a diameter within the range of from about 0.009" to about 0.018", although larger diameters may also be used particularly for the first control line **108**.

The distal control line **110** is advanced through an introducer sheath into the great cardiac vein **28** and then through anastomotic connections **29** into the middle cardiac vein **30**. Continued advancement results in the tip of the distal control line **110** emerging from the ostium **24** of the coronary sinus **22**. The control line **110** is then harnessed with a snare and pulled retrogradely through the delivery catheter as illustrated in FIG. **5**. The body **102** is then pulled into the coronary venous system. The body is preferably larger in diameter than the first and second control lines **108** and **110**, and preferably elliptical or otherwise noncircular in cross section. This shape enlarges the transverse tissue contact surface area and reduces the risk of erosion when tension is applied to the loop. Both the proximal and distal ends of the loop are threaded through a locking clip **112**. A dilator is used to push the clip **112** through the delivery catheter to the level of the coronary sinus ostium. Using counter traction on the dilator and the first and second control lines **108** and **110**, the clip **112** is cinched on the loop until the requisite degree of tension is produced. Finally, the device is separated from the delivery system using a cutting tool to cut the first and second control lines **108** and **110**, and possibly proximal and distal ends **104** and **106** to the extent they extend proximally from clip **112**.

The overall length of the embodiment illustrated in FIG. **5** should be sufficient that both of the first control line **108** and second control line **110** can extend outside of the patient, while the body **102** extends throughout the pathway of the ventricular girdle **100** as illustrated in FIG. **6**. For a percutaneous femoral vein access, the overall length of the device is therefore preferably at least about 200 cm, and generally within the range of from about 220 cm to about 260 cm. The length of the body **102** from proximal end **104** to distal end **106** is preferably sufficient to form a closed loop as illustrated in FIG. **6**. Although both heart size and the shape of the vascular pathway will vary from individual to individual, the length of the body **102** is generally within the range of from about 6 cm to about 12 cm. The body **102** may be injection molded, extruded as a tube, or coextruded over the wire which forms first and second control lines **108** and **110**. Preferably, the body **102** either comprises or is coated with a material which is sufficiently compliant to minimize trauma to the vascular intima. Also, the transverse width of a tissue contacting surface **114** on body **102** is preferably sufficient to distribute compressive force to minimize the risks of localized pressure necrosis within the coronary veins.

In each of the foregoing implantation methods, the physician preferably monitors the degree of regurgitation during the step of tightening the implant. Although any reduction in mitral regurgitation may be desirable, regurgitation is preferably reduced to something less than moderate (less than 2+). In any event, at least a one grade reduction is preferably achieved. On the other hand, reconfiguration of the implant should not be accomplished to an extent sufficient to produce mitral stenosis, or any flow limitation of hemodynamic significance.

Thus, the method of implantation preferably further comprises the steps of monitoring the degree of mitral regurgitation during the implantation and/or reconfiguration steps. The degree of mitral regurgitation may be monitored such as by transesophageal echo cardiography, surface echo cardiography, intracardiac echo cardiography, fluoroscopy using radiocontrast in the left ventricle (LV gram), or left atrial or pulmonary capillary wedge pressure tracings, as are understood in the art, during the incremental restriction of the mitral annulus and/or left ventricle step. Once a sufficient reduction in regurgitation has been achieved for a particular patient in the physician's judgement, the device is locked and the proximal extension of the forming element is severed from the device and removed from the patient.

The method may additionally comprise the step of measuring the coronary sinus and/or other coronary vein, and selecting an appropriately sized implant from an array of implants of varying sizes. The appropriately sized implant is thereafter positioned within the target vein. The implant is thus preferably provided in a graduated array of sizes, so that the optimal size can be selected for each patient. The size of the coronary sinus or other vein can be measured using any of a variety of techniques, such as echo cardiogram, MRI, CT scan, or angiography as is understood in the art.

As a further aspect to the present invention, the implant is preferably combined with an appropriate drug therapy for treating congestive heart failure. Residual regurgitation and other hemodynamic functions are preferably measured following implantation of the implant of the present invention. Heart medications are preferably adjusted to take into account the reduction in regurgitation and/or reduction in left ventricle volume in formulating an ongoing drug therapy for the patient.

In accordance with further aspect of the present invention, there is provided a method of constricting the left ventricle. Left ventricular constriction may be desirable in patients without mitral regurgitation. One implementation of this method comprises implanting the ventricular girdle **100** as illustrated, for example, in FIGS. **5** through **6** and previously discussed herein.

Any of the embodiments disclosed herein may additionally be provided with one or more externally facing electrically conductive axially extending strips or annular bands, to enable the device **40** to function additionally as a cardiac pacing or other cardiac electrode. The electrically conductive band or bands are placed in electrical communication with a pacing source or diagnostic instrument by way of one or more electrical conductors extending away from the device **40**. The conductors may be electrically connected to any of a wide variety of electronic cardiac rhythm management devices, which are well known in the art.

Although the present invention has been described in terms of certain preferred embodiments, it may be incorporated into other embodiments or performed through other steps by persons of skill in the art in view of the disclosure herein. The scope of the invention is therefore not intended to be limited by the specific embodiments disclosed herein, but is intended to be defined by the full scope of the following claims.

What is claimed is:

1. A medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus, comprising:

an elongate body, having a proximal end region and a distal end region, each of the proximal and distal end regions dimensioned to reside completely within the vascular system, the elongate body being movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus to a second configuration for remodeling the mitral valve annulus proximate the coronary sinus;

a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration; and

a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus.

2. The medical apparatus according to claim **1**, wherein the forming element is secured to the elongate body at a point of attachment and the forming element is movable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations.

3. The medical apparatus according to claim **2**, wherein the forming element is adapted to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration.

4. The medical apparatus according to claim **3**, further comprising a cutting tool which is adapted to sever the forming element while the elongate body is positioned at least in part within the coronary sinus.

5. A medical apparatus as in claim **1**, wherein the elongate body defines an arc when in the remodeling configuration.

6. A medical apparatus as in claim **5**, wherein a best fit constant radius curve corresponding to the arc has a radius within the range of from about 10 mm to about 20 mm.

7. A medical apparatus as in claim **1**, wherein the lock comprises a locking ring.

8. A medical apparatus as in claim **1**, wherein the lock comprises an interference fit.

9. A medical apparatus as in claim **1**, wherein the lock comprises an adhesive bond.

10. A medical apparatus as in claim **1**, wherein the lock comprises a suture knot.

11. A medical apparatus as in claim **1**, wherein the lock comprises a clamp.

12. A medical apparatus as in claim **1**, wherein the lock comprises a compression fit.

13. A medical apparatus as in claim **1**, wherein the lock comprises a ratchet.

14. A medical apparatus as in claim **1**, wherein the lock comprises an engagement surface, which is movable between a first, disengaged configuration and a second, engaged configuration.

15. A medical apparatus as in claim **1**, wherein the lock is biased in a locked direction.

16. A medical apparatus as in claim **1**, wherein the lock is biased in an unlocked direction.

17. A medical apparatus as in claim **1**, further comprising a coating on the body.

18. A medical apparatus as in claim **1**, wherein the apparatus is movable from the implantation configuration to the remodeling configuration in response to proximal retraction of the forming element.

19. A medical apparatus as in claim **1**, wherein the apparatus is movable from the implantation configuration to the remodeling configuration in response to distal advancement of the forming element.

20. A medical apparatus as in claim **1**, further comprising an anchor for retaining the apparatus at a deployment site within a vessel.

21. A medical apparatus as in claim **20**, wherein the anchor comprises a distal extension of the apparatus.

22. A medical apparatus as in claim **20**, wherein the anchor comprises a friction enhancing surface structure for engaging the wall of the vessel.

23. A medical apparatus as in claim 20, wherein the anchor comprises at least one barb for piercing the wall of the vessel.

24. A medical apparatus as in claim 1, wherein the apparatus has an axial length of no more than about 10 cm.

25. A medical apparatus as in claim 24, wherein the maximum cross sectional dimension through the apparatus is no more than about 10 mm.

26. A medical apparatus as in claim 1, further comprising an axially extending support in the body, attached to the forming element.

27. A medical apparatus as in claim 1, wherein the forming element comprises a polymeric strand.

28. A medical apparatus as in claim 1, wherein the forming element comprises a metal wire.

29. A medical apparatus as in claim 1, wherein the forming element comprises a multifilament structure.

30. A medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus, comprising:

an elongate body, having a proximal end region and a distal end region, each of the proximal and distal end regions dimensioned to reside completely within the vascular system, the elongate body being movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus and a second configuration for remodeling the mitral valve annulus proximate the coronary sinus;

a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration, the forming element secured to the elongate body at a point of attachment and moveable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations, the forming element adapted to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration; and

a cutting tool which is adapted to sever the forming element while the elongate body is positioned at least in part within the coronary sinus;

wherein the elongate body maintains a substantially constant length when manipulated by the forming element between the first and second configurations.

31. A medical apparatus for remodeling a mitral valve annulus adacent to the coronary sinus, comprising:

an elongate body, having a proximal end region and a distal end region, each of the proximal and distal end regions dimensioned to reside completely within the vascular system, the elongate body being movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus and a second configuration for remodeling the mitral valve annulus proximate the coronary sinus;

a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration, the forming element secured to the elongate body at a point of attachment and movable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations, the forming element adapted to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration; and

a cutting tool adapted to sever the forming element while the elongate body is positioned at least in part within the coronary sinus;

wherein the elongate body is relatively non-compressible while the elongate body is adjusted between the first and second configurations.

32. A medical apparatus for remodeling a mitral valve annulus adjacent to the coronary sinus, comprising:

an elongate body, having a proximal end region and a distal end region, each of the proximal and distal end regions dimensioned to reside completely within the vascular system, the elongate body being movable from a first configuration for transluminal delivery to at least a portion of the coronary sinus and a second configuration for remodeling the mitral valve annulus proximate the coronary sinus;

a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration, the forming element secured to the elongate body at a point of attachment and movable relative to the elongate body in order to adjust the elongate body within the coronary sinus between the first and second configurations, the forming element adapted to be severed while the elongate body is positioned at least in part within the coronary sinus in the second configuration; and

a cutting tool adapted to sever the forming element while the elongate body is positioned at least in part within the coronary sinus;

wherein the elongate body is interchangeably adjustable between the first and second configurations within the coronary sinus.

33. A method of performing transluminal mitral annuloplasty, comprising the steps of:

selecting a prosthesis having a proximal end and a distal end;

providing a deployment system cooperating with the prosthesis and which is adapted to at least in part deliver the prosthesis into the coronary sinus;

inserting the deployment system and prosthesis into the venous system;

transluminally advancing the prosthesis into at least a portion of the coronary sinus;

tightening the prosthesis to generate a compressive force on the adjacent cardiac musculature and influence the size of the mitral valve annulus, the tightening step achieved by proximally retracting a forming element while resisting proximal movement of the prosthesis; and

locking the prosthesis after the step of tightening;

wherein the prosthesis is interchangeably adjustable between tightening to generate the compressive force, and untightening to relieve the compressive force while the prosthesis is positioned within the coronary sinus.

34. A method as in claim 33, further comprising the step of percutaneously accessing the venous system prior to the transluminally advancing step.

35. A method as in claim 33, wherein the accessing step is accomplished by accessing one of the internal jugular, subclavian and femoral veins.

36. A method as in claim 33, further comprising the step of limiting diastolic expansion of the left ventricle.

37. A method as in claim 33, wherein the transluminally advancing step is accomplished using a catheter.

38. A method as in claim 33, wherein the locking step comprises moving an engagement surface from a disengaged configuration to an engaged configuration.

39. A method as in claim 33, wherein the locking step comprises providing an interference fit.

40. A method as in claim 33, wherein the locking step comprises providing an adhesive bond.

41. A method as in claim 33, wherein the locking step comprises providing a knot.

42. A method as in claim 33, wherein the locking step comprises providing a compression fit.

43. A method as in claim 33, further comprising the steps of first measuring the coronary sinus and then selecting an appropriately sized prosthesis prior to the inserting step.

44. A method as in claim 33, further comprising the step of measuring hemodynamic function following the locking step.

45. A method as in claim 44, further comprising the step of determining an ongoing drug therapy taking into account the post implantation hemodynamic function.

46. A method of performing trasluminal mitral annuloplasty, comprising the step of:

selecting a prosthesis having a proximal end and a distal end;

providing a deployment system cooperating with the prosthesis and which is adapted to at least in part deliver the prosthesis into the coronary sinus;

inserting the deployment system and prosthesis into the venous system;

transluminally advancing the prosthesis into at least a portion of the coronary sinus;

tightening the prosthesis to generate a compressive force on the adjacent cardiac musculature and influence the size of the mitral valve annulus, the tightening step achieved by proximally retracting a forming element while resisting proximal movement of the prosthesis; and

locking the prosthesis after the step of tightening;

wherein the prosthesis maintains a substantially constant length when tightened to generate the compressive force.

* * * * *

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Cox

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(45) **Date of Patent: Jun. 26, 2001**

(54) **MITRAL VALVE ANNULOPLASTY RING AND METHOD OF IMPLANTING**

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(21) Appl. No.: **09/399,444**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61F 2/24**

(52) **U.S. Cl.** **128/898**; 623/2.36; 623/904

(58) **Field of Search** 623/2.36–3.1; 128/898

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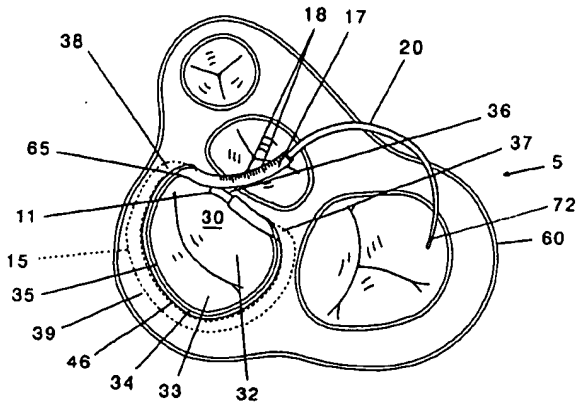
(74) *Attorney, Agent, or Firm*—Boyd D. Cox

(57) **ABSTRACT**

A mitral valve annuloplasty ring and method for implanting a mitral valve annuloplasty ring to treat mitral insufficiency by reestablishing the normal shape and contour of the mitral valve annulus. The annuloplasty ring is flexible and can be readily adjusted to different sizes and shapes. The method substantially eliminates scarring subsequent to the annuloplasty procedure to maintain flexibility of the ring and the annulus indefinitely.

10 Claims, 6 Drawing Sheets



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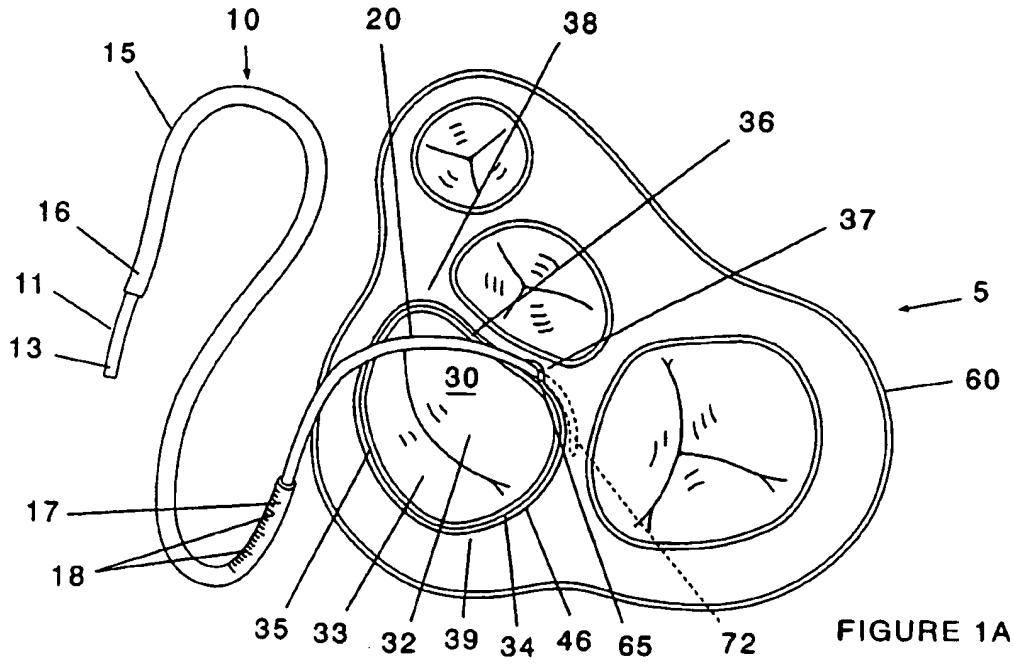


FIGURE 1A

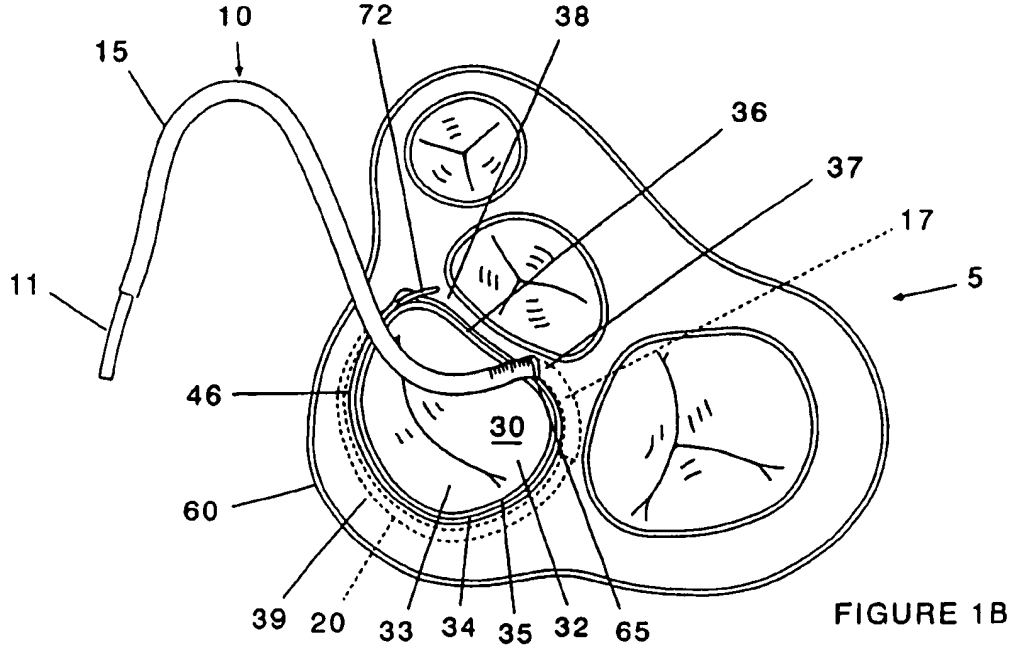


FIGURE 1B

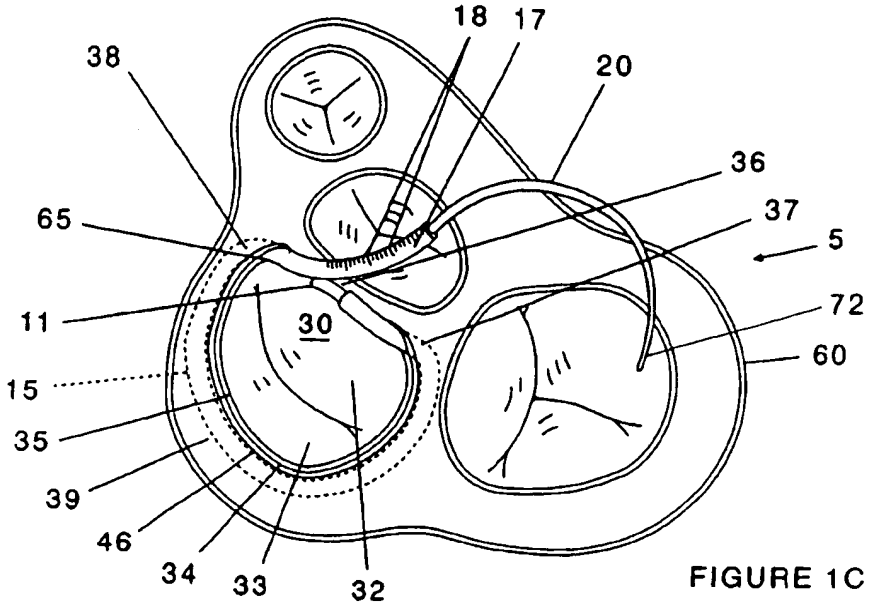
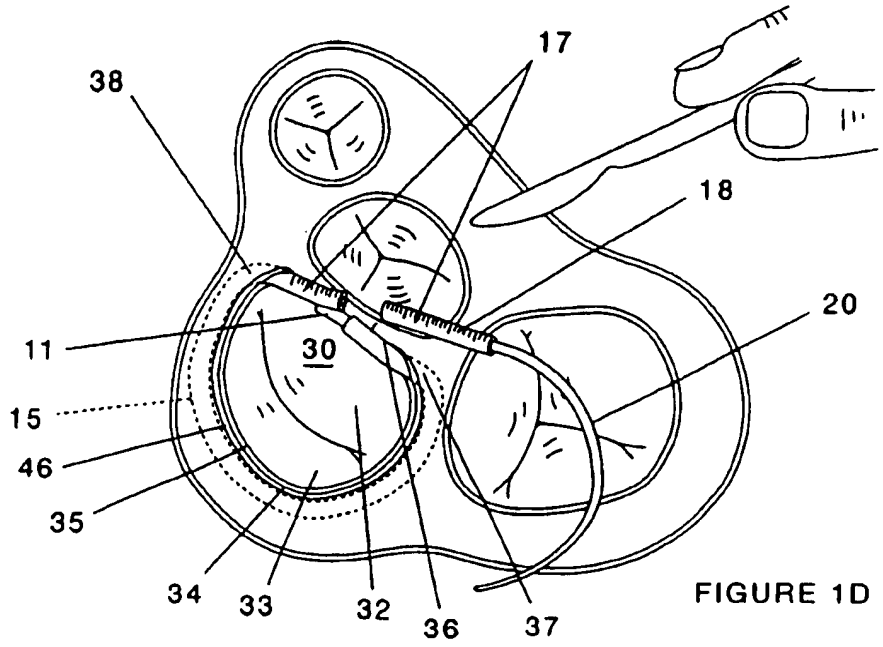


FIGURE 1C



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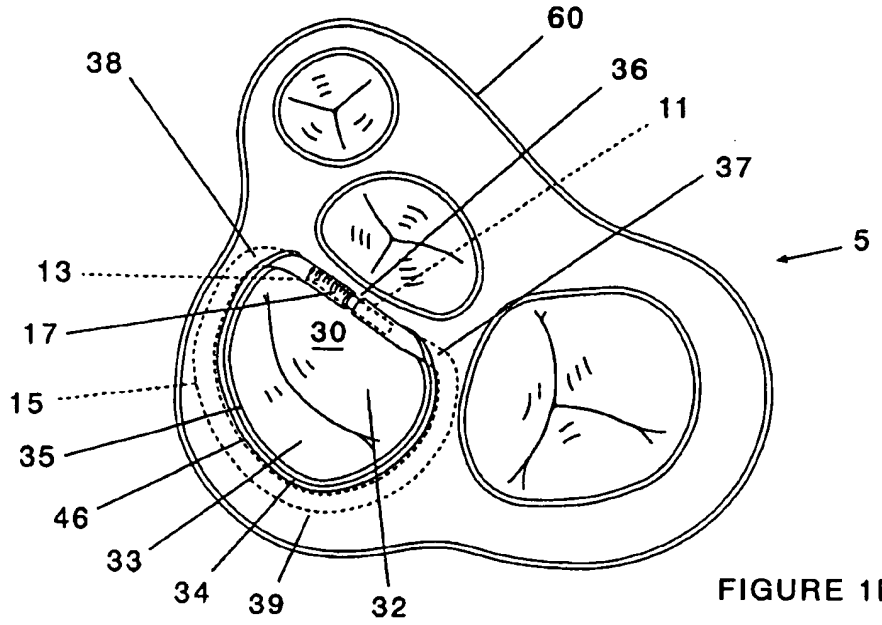


FIGURE 1E

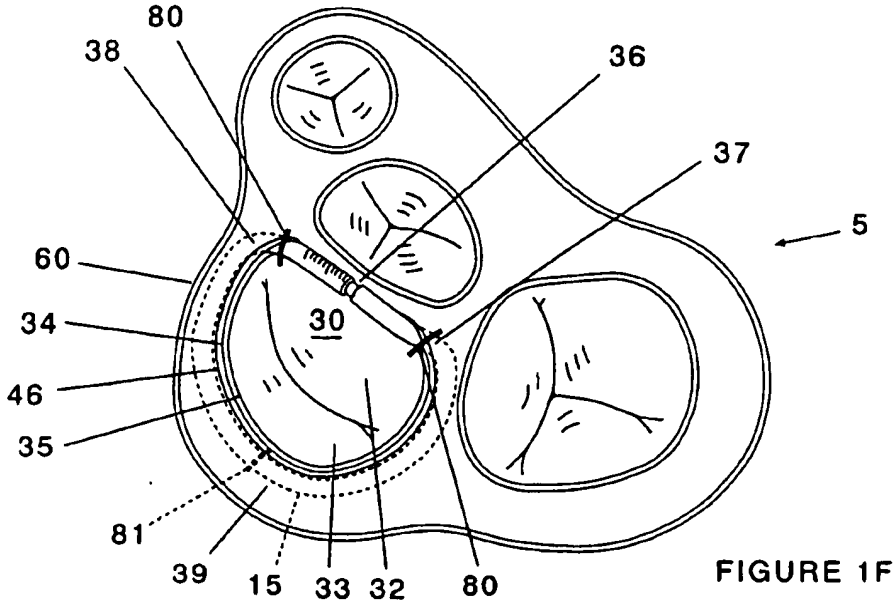


FIGURE 1F

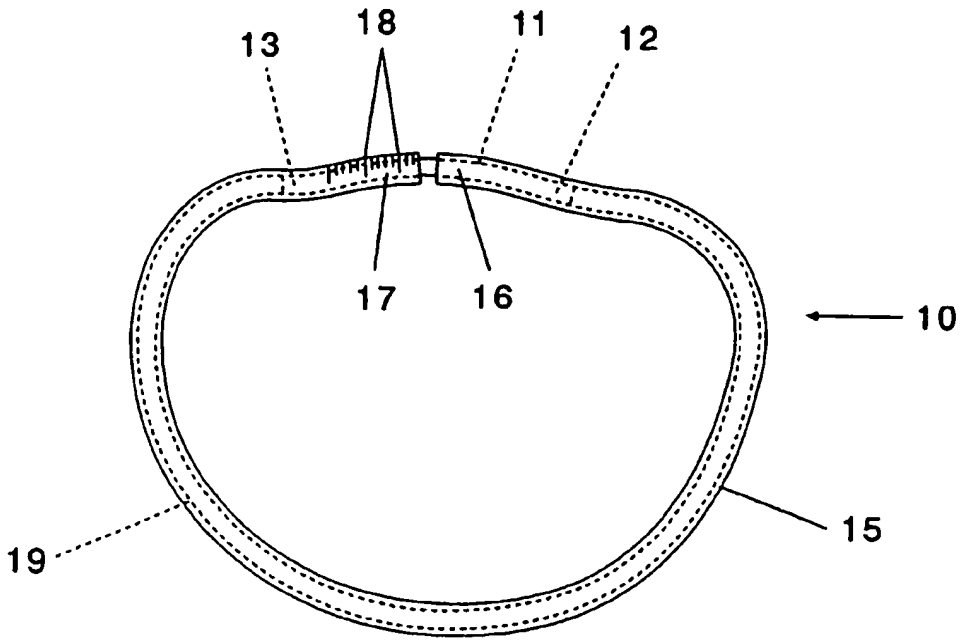


FIGURE 2A

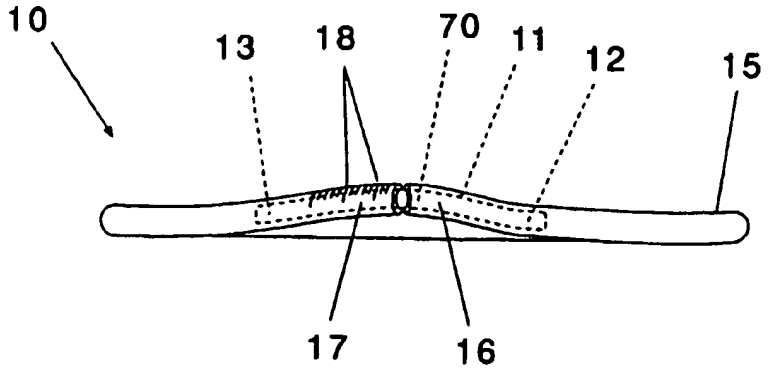


FIGURE 2B

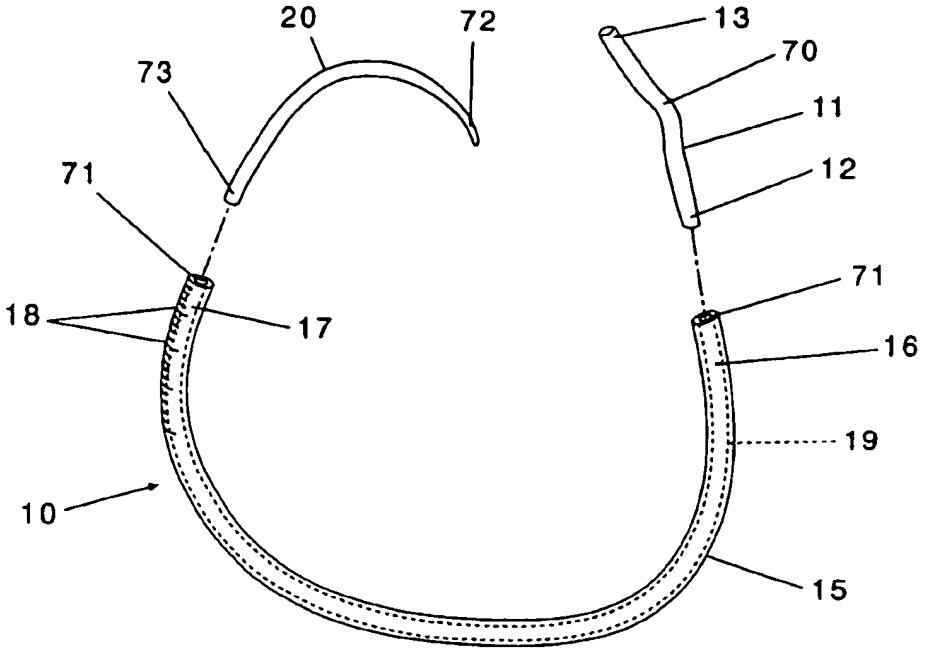


FIGURE 3

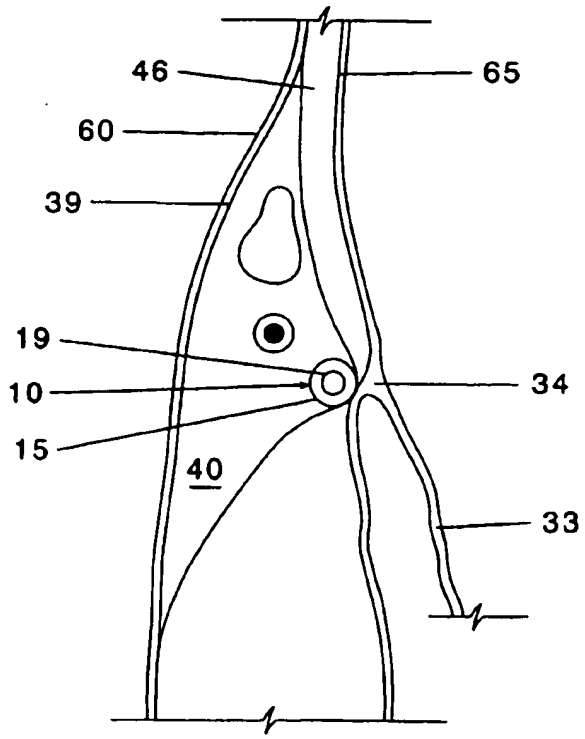


FIGURE 4

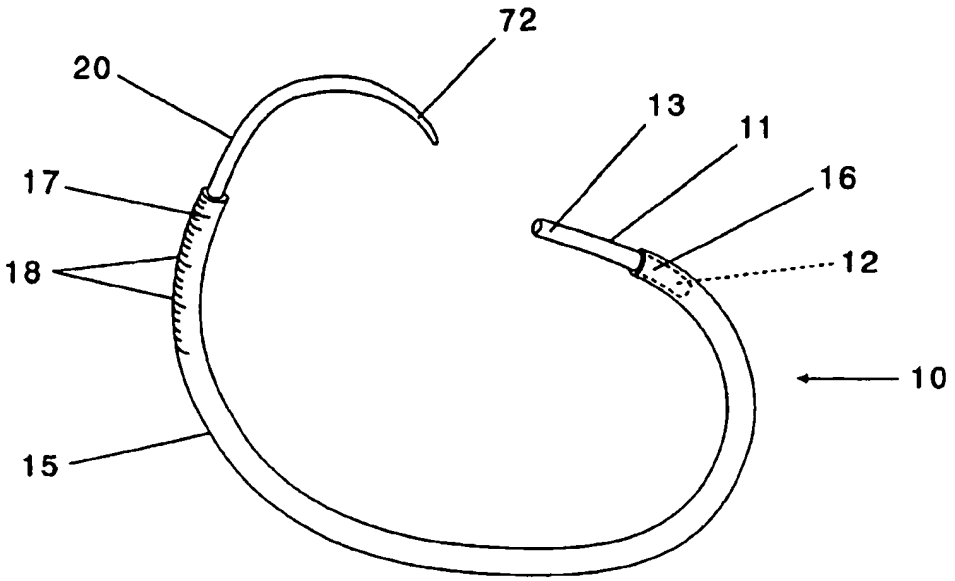


FIGURE 5

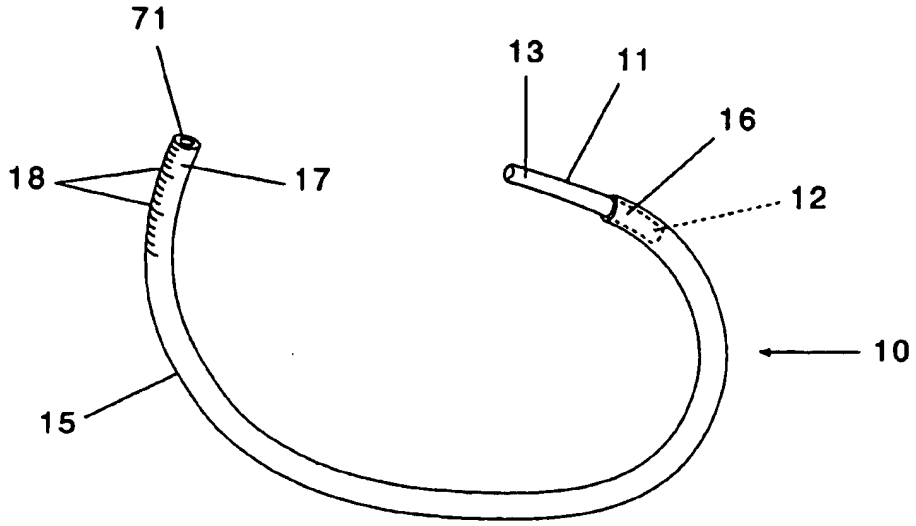


FIGURE 6

MITRAL VALVE ANNULOPLASTY RING AND METHOD OF IMPLANTING

This is a continuation of application Ser. No. 09/097,763 filed Jun. 16, 1998. The entire disclosure of the aforementioned application is hereby incorporated by reference herein.

BACKGROUND

The present invention is directed to a mitral valve annuloplasty ring and a method for implanting a mitral valve annuloplasty ring to treat mitral insufficiency in a patient. Mitral insufficiency, also known as mitral regurgitation, is a common cardiac abnormality wherein the heart's mitral valve does not properly close.

In a normally functioning heart, oxygenated blood passes from the left atrium through the opened mitral valve and into the left ventricle when the left ventricle is in a relaxed state. When the left ventricle contracts, the blood is pushed out of the left ventricle thereby closing the mitral valve to prevent blood flowing back or regurgitating into the left atrium. From the left ventricle, the oxygenated blood is pumped out of the heart and directed to the rest of the body.

With mitral insufficiency, the mitral valve does not fully close and a portion of blood leaks back into the left atrium when the left ventricle contracts. As a result, the heart has to work harder by pumping not only its regular volume of blood, but also the extra volume of blood that regurgitates back into the left atrium. The added workload creates an undue strain on the left ventricle. This strain can eventually wear out the heart and result in death when the condition is prolonged and severe enough. Consequently, a properly functioning mitral valve is critical to the pumping efficiency of the heart.

Mitral valve annuloplasty is a well known approach for treating mitral insufficiency, although other treatments are used which include replacing the mitral valve, repairing the mitral valve leaflets, and shortening or replacing the chordae tendinae. Mitral valve annuloplasty is the reparation of the mitral valve annulus which effects full closure of the leaflets by reestablishing the size and shape of the normal mitral valve annulus. Such an annuloplasty most commonly incorporates the use of a mitral annuloplasty ring wherein the ring is implanted on the mitral valve annulus.

There are three basic types of mitral annuloplasty rings used in annuloplasty procedures. They include a rigid ring, a flexible ring and a combined ring that has both a flexible component and a rigid component.

Due to their inflexibility, the rigid rings dictate the shape and contour of the mitral valve. The native mitral valve annulus flexes in response to the movement of the heart. However, with a rigid ring the annulus is not able to flex normally or move freely with the pumping action of the heart. As a result of the rigidity, the physiologic factors that normally shape the mitral valve annulus are not allowed to take precedence in shaping the valve.

Another drawback with rigid rings is that they can induce a heart condition known as systolic anterior motion in patients having a mitral valve posterior leaflet that is too "tall". During ventricular contraction, the posterior leaflet pushes the anterior leaflet in a direction opposite to the anterior leaflet's normal movement, resulting in the obstruction of the left ventricle's outflow tract.

Overall, rigid annuloplasty rings do not allow the mitral valve annulus to reestablish its normal shape and form as dictated by the action of the heart pumping. The shape and contour of the annulus is established by the inflexible shape and form of the ring itself.

Flexible rings made of Dacron cloth, unlike the rigid rings, can allow the mitral valve annulus to move and flex as the heart contracts and relaxes. However, several drawbacks still exist. Proper shape and contour of the annulus is necessary in order for the mitral valve leaflets to close effectively. One shortcoming of the flexible ring is its predisposition to crimp during implantation. Crimping can be detrimental to the valve annulus, sometimes resulting in a mitral orifice that is too small. This can lead to stenosis of the valve. Furthermore, neither the flexible rings nor the combined rings will remain flexible indefinitely after annuloplasty. Since the rings are secured in place by a line of sutures attached directly to the annulus, scarring and resultant stiffening of the annulus inevitably develops. This loss of flexibility impedes the normal flexing and movement of the heart, particularly the left ventricle and, therefore, the heart cannot function optimally.

SUMMARY

The annuloplasty ring of the present invention is a combined ring which comprises a first section that is substantially rigid and a second flexible section. The ring can be readily adjusted to fit the annulus of any particular patient. The method of implanting the annuloplasty ring of the present invention comprises installing a ring within the fat pad of the atrioventricular groove which surrounds the mitral valve annulus. The method does not require a series of sutures extending through the mitral valve annulus tissue to hold the ring in place. Resultant scarring and stiffening of the annulus is thereby substantially eliminated.

The ring of the present invention when combined with the method of the present invention is positioned in the fat pad of the atrioventricular groove adjacent to the mitral valve annulus. The flexible section of the ring extends adjacent to the flexible posterior portion of the annulus, while the rigid section of the ring spans the substantially rigid inter-trigone section of the annulus. Since the flexible section of the ring is held in the atrioventricular groove of the posterior section of the annulus, it is not necessary to suture the flexible section directly to the mitral valve annulus. As a result, scarring of the annulus is substantially eliminated, thereby allowing the ring and annulus to remain flexible indefinitely. As in the normal heart, this flexibility enables the mitral valve annulus to flex in several planes during contraction and relaxation of the heart. The result is better postoperative functioning of the mitral valve and better postoperative functioning of the left ventricle, as well.

It is an object of the present invention to provide an annuloplasty ring that reestablishes the normal shape and contour of the mitral valve annulus.

It is a further object of the present invention to provide a method for performing an annuloplasty that substantially eliminates scarring of the mitral valve annulus tissue to preclude the loss of flexibility following the annuloplasty.

It is a further object of the present invention to provide a method for implanting the annuloplasty ring that allows the ring to maintain flexibility indefinitely.

It is a further object of the invention to provide an annuloplasty ring that is flexible enough to allow the mitral valve and annulus to flex through different planes, yet positioned such that the shape and contour of a normal mitral valve annulus is reestablished.

It is a further object of the present invention to provide a flexible annuloplasty ring that does not crimp during implantation.

It is a further object of the present invention to provide an annuloplasty ring that can be flexed in all manner that the native mitral valve annulus flexes.

It is a further object of the present invention to provide an annuloplasty ring and method of implanting the ring that maintains flexibility of the ring and the mitral valve annulus indefinitely.

It is a further object of the present invention to provide a method for implanting the annuloplasty ring that minimizes scarring of the mitral valve annulus and nearby tissue.

It is a further object of the present invention to provide an annuloplasty ring that assumes the shape of the normal mitral valve annulus to allow for effective functioning of the valve.

It is a further object of the present invention to provide an annuloplasty ring and method of implanting the ring that result in effective coaptation of the anterior and posterior leaflets of the mitral valve.

It is a further object of the present invention to provide an annuloplasty ring and method of implanting an annuloplasty ring that do not impede the movement of the left ventricle's base when the ventricle is contracting and relaxing, thereby allowing effective functioning of the left ventricle.

It is a further object of the present invention to provide an annuloplasty ring and a method of surgically implanting an annuloplasty ring that allow the base of the left ventricle to assume its full range of movement when contracting and relaxing to allow effective functioning of the left ventricle.

It is a further object of the present invention to provide an annuloplasty ring that allows the left ventricle to move naturally as the heart pumps and allows the mitral valve annulus to flex freely in response to the movement of the left ventricle.

It is a further object of the present invention to provide an annuloplasty ring and a method of implanting the annuloplasty ring that does not require a plurality of sutures along the posterior portion of the mitral valve annulus to secure the ring in place.

It is a further object of the present invention to provide an annuloplasty ring that can be readily adjusted in size.

It is a further object of the present invention to provide an annuloplasty ring that can be readily adjusted in shape by adjusting the circumference of the ring.

It is a further object of the present invention to provide a kit for an annuloplasty ring that reestablishes the normal shape and contour of the mitral valve annulus.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the accompanying drawings in which are shown illustrative embodiments of the invention and from which novel features and advantages will be apparent.

FIGS. **1A–1F** are cutaway views of the heart as seen from the atrial position depicting a preferred method of implanting the mitral valve annuloplasty ring in the atrioventricular groove.

FIG. **2A** is a top view of a preferred embodiment of the mitral valve annuloplasty ring of the present invention in a closed configuration.

FIG. **2B** is a side view of the mitral valve annuloplasty ring in a closed configuration.

FIG. **3** is an exploded view of the mitral valve annuloplasty ring with needle.

FIG. **4** is a schematic cross sectional side view of a portion of the heart depicting the atrioventricular groove with the annuloplasty ring implanted therein.

FIG. **5** is a view of the mitral valve annuloplasty ring in a surgical configuration.

FIG. **6** is a view of the mitral valve annuloplasty ring in an open configuration.

DETAILED DESCRIPTION

The left ventricle is the main pumping chamber of the heart. Oxygenated blood from the lungs enters the left atrium and passes into the left ventricle through the mitral valve. The blood is pumped from the left ventricle to the rest of the body.

As shown in FIGS. **1A–1F**, the mitral valve (**30**) is a one way passive valve comprising a pair of leaflets, including a larger anterior leaflet (**32**) and a smaller posterior leaflet (**33**). The leaflets open and close in response to pressure differences in the heart (**5**) on either side of the mitral valve (**30**). The base of each anterior (**32**) and posterior (**33**) leaflet is attached to the mitral valve annulus (**34**).

The contour of the mitral valve annulus (**34**) refers to the outline or form of the annulus (**34**) when viewed in the general plane of the annulus (**34**). The shape of the annulus (**34**) is that shape viewed from the atrial side of the mitral valve (**30**), "looking down" on the mitral valve annulus (**34**).

The mitral valve annulus (**34**) includes a posterior portion (**35**) and an anterior portion (**36**). The anterior portion (**36**), also known as the inter-trigone segment or section, is a generally straight, substantially rigid segment. The posterior portion (**35**) of the annulus (**34**) is a flexible, curvilinear segment that encompasses a larger proportion of the annulus circumference than the anterior portion (**36**). The right (**37**) and left (**38**) fibrous trigones mark the ends of the generally straight segment and define the intersection points between the posterior (**35**) and anterior portions (**36**).

Referring to FIGS. **2A** and **2B**, there is shown a preferred embodiment of the annuloplasty ring (**10**) comprising the present invention. The ring (**10**) comprises a first section (**11**) and a second section (**15**). The first section (**11**) has a first end (**12**) and a second end (**13**), while the second section (**15**) includes a proximal end (**16**) and a distal end (**17**). A means for sizing the annuloplasty ring (**10**) includes measurement indicia (**18**) extending inwardly from an outermost edge of the second section's distal end (**17**). The annuloplasty ring (**10**) also includes a detachable needle (**20**) having a tip (**72**) and an attaching end (**73**) as shown in FIG. **3**.

The annuloplasty ring (**10**) comprises a first means for joining the second end of the first section to the distal end of the second section and a second means for joining the first end of the first section to the proximal end of the second section. The ring (**10**) also comprises a third means for joining the second end of the second section to the needle.

In one preferred embodiment, the first means for joining the second end of the first section to the distal end of the second section, the second means for joining the first end of the first section to the proximal end of the second section, and the third means for joining the second end of the second section to the needle comprise frictional engagements.

The frictional engagements include a hollow inner portion (**19**) in the second section (**15**) having exterior openings (**71**) at the proximal (**16**) and distal (**17**) ends. The hollow inner portion (**19**) can extend the entire length of the second section (**15**) or alternately, it can be limited to the ends (**16, 17**) of the second section (**15**). The hollow portion (**19**) has an inner diameter that is approximately equal to the outer diameter of the first (**12**) and second (**13**) ends of the first section (**11**) and also that is approximately equal to the outer diameter of the attaching end (**73**) of the needle (**20**).

The exterior openings (**71**) of the hollow inner portion (**19**) on the proximal end (**16**) of the second section (**15**) receives the first end (**12**) therein, while the exterior opening (**71**) of the hollow inner portion (**19**) on the distal end (**17**) receives the second end (**13**) of the first section and, alternately, the attaching end (**73**) of the needle (**20**). When the ends (**12, 13**) of the first section (**11**) are inserted through the exterior openings (**71**) into the hollow inner portion (**19**), a frictional engagement is created between the respective inner and outer diameters which secures the ends of the

sections (11, 15) together. Likewise, when the attaching end (73) of the needle (20) is inserted through the exterior opening (71) into the hollow inner portion (19) of the distal end (17), the needle (20) is held within the hollow inner portion (19) by frictional engagement.

Although the first means for joining the second end of the first section to the distal end of the second section, the second means for joining the first end of the first section to the proximal end of the second section, and the third means for joining the second end of the second section to the needle comprise frictional engagements, any suitable and separate types of means could be used instead.

The first (11) and second (15) sections are elongated. In one preferred embodiment, the first section (11) has a bow or bend (70) in the center region. The bow (70) is offset approximately 1.0 mm from a reference plane in which the first (12) and second (13) ends are located. In another preferred embodiment, the first section of the ring is straight and does not have a bow.

The first section (11) is made from a substantially rigid material. It is preferable that the material is able to maintain its rigidity indefinitely and also preferable that it is inert or compatible with body tissues. Examples of materials that could be used for the first section (11) are titanium, stainless steel, pyrolytic carbon and various plastics. Also, other suitable materials of choice could be used, as well.

The material comprising the second section (15) is flexible and is capable of being affixed to the first section. Preferably, the material is inert or compatible with body tissues. Examples of materials that could be used for the second section include silastic, polyethylene, Dacron and Teflon. Also, other suitable materials of choice could be used, as well.

The annuloplasty ring (10) of the present invention reestablishes the normal shape and contour to the mitral valve annulus (34). The first section (11) of the annuloplasty ring (10) is adjacent to the inter-trigone section (36) after implantation, as shown in FIGS. 1A–1F. The curvature of the bow (70) is oriented to conform to the portion of the mitral valve annulus (34) that is located adjacent to the aortic valve root. Both the first section (11) and the inter-trigone section (36) are substantially rigid. Since the inter-trigone section (36) does not normally bend in response to the movements of the heart, it is, therefore, not required for the first section (11) to bend or flex either.

The second section (15) is implanted adjacent to the posterior portion (35) of the annulus. Both the posterior portion (35) and the second section (15) are flexible and, as a result, can flex and move with the natural movements of the heart, as the left ventricle relaxes and contracts. Furthermore, the method of implanting the annuloplasty ring within the fat pad (40) of the atrioventricular groove (39), as shown in FIG. 4, ensures that the annulus and the second section (15) of the ring (10) will remain flexible indefinitely.

Referring again to FIGS. 1A–1F, the needle (20) acts as a leader guide to implant the ring (10) in the proper location and position in the atrioventricular groove (39) around the mitral valve annulus (34). The tip (72) of the needle is preferably a round-tip which is sharp enough to penetrate the tissue for implantation, yet blunt enough to maneuver within the atrioventricular groove without damaging critical areas.

The size and shape of the annuloplasty ring (10) can be adjusted. Using the measurement indicia (18) on the second section (15) as a guide, the appropriate length of the section is established, then any unnecessary length on the second section (15) can be removed by cutting, as shown in FIG. 1D. By changing the length of the second section (15), the circumference of the annuloplasty ring is also changed.

As shown in FIG. 2A, the second means for joining the first end of the first section to the proximal end of the second section and the first means for joining the second end of the first section to the distal end of the second section secures the ends (12, 13) of the first section (11) to the respective ends (16, 17) of the second section (15) to form a closed loop. In one preferred embodiment in which the first and second means for joining comprise frictional engagements, the proximal (16) and distal (17) ends of the second section are preferably disposed adjacent to each other at a center region of the first section (11), thereby covering a substantial portion of the first section (11). Alternately, the second end (13) of the first section (11) can be free and unattached while the distal end (17) of the second section (15) is attached to the needle (20) for performing the annuloplasty as shown in FIG. 5.

The length of the first section (11) is shorter than the length of the second section (15). The length of first section (11) can vary, but it is preferred that its length be no more than about 50–75% of the length of the inter-trigone section (36) of the mitral valve annulus being repaired. The requisite proportion for a particular annuloplasty ring will depend on the flexibility of the second section (15). As for example, the more flexible the material forming the second section (15), the longer the length of the first section (11) should be relative to the length of the inter-trigone section (36). Conversely, the less flexible the material of the second section (15), the shorter the relative length of the first section (11) should be relative to the length of the inter-trigone portion (36).

The lengths of the two sections can be varied relative to each other in order to achieve various shapes for the closed loop of the annuloplasty ring (10). For example, by lengthening the first section (11) relative to the length of the second section (15), the annuloplasty ring will become "flatter" as characterized by a smaller anterior to posterior distance.

In one preferred embodiment of the present invention, the first section (11) has a length of approximately 1.5 cm and an overall diameter of approximately 6 mm. The diameter can, however, vary so long as it fits the mitral valve annulus under repair and it precludes inadvertent deformation or breakage of the ring.

In one preferred embodiment, the indicia (18) are markings spaced at intervals of about 1.0 mm. However, the intervals could be spaced at any desired distance, extending for any desired length along the second section (15).

An open configuration of the annuloplasty ring (10) is shown in FIG. 6 wherein the first section (11) has its first end (12) attached to the second section's proximal end (16). The second end (13) of the first section (11) and the distal end (17) of the second section (15) are unattached.

A closed configuration, shown in FIG. 2A, comprises the first end (12) of the first section (11) being attached to the proximal end (16) of the second section (15) and the second end (13) of the first section (11) being attached to the distal end (17) of the second section (15). In the closed configuration, the annuloplasty ring (10) forms the closed loop. After the annuloplasty procedure, the ring (10) is in its closed configuration.

In FIG. 5, the annuloplasty ring (10) of the present invention is shown in a surgical configuration in which the first end (12) of the first section (11) is attached to the proximal end (16) of the second section (15) and the needle (20) is attached to the distal end (17) of the second section (15). The second end (13) of the first section (11) is unattached. The surgical configuration is designated primarily for use during the annuloplasty procedure.

After the annuloplasty ring (10) is implanted as in FIG. 1E, the first section (11) is in alignment with the inter-trigone section (36) of the mitral valve annulus (34) such that the bow (70) conforms to the contour of the annulus (34)

adjacent to the aortic valve root. The inter-trigone section (36) which extends between the left (38) and right (37) fibrous trigones is substantially rigid, as is the first section (11) of the ring. The second section (15) is primarily implanted around the posterior portion (35) of the annulus (34) and within the fat pad (40) of the atrioventricular groove (39) as shown in FIG. 4. Along with the posterior portion (35) of the annulus (34), the second section (15) is allowed to move and flex freely with the movements of the heart.

Referring to FIGS. 1A–1E, the annuloplasty ring (10) is installed adjacent to the mitral valve annulus (34) and within the fat pad (40) of the atrioventricular groove (39). After the ring (10) is implanted, the second section (15) is cut to the appropriate size for the patient. The distal end (17) of the second section (15) is then attached to the first section (11). Preferably, the ring (10) is sutured to the annulus at the left and right fibrous trigones. However, this suturing may be avoided if deemed not necessary.

To implant the annuloplasty ring in a patient, the needle (20) is attached to the distal end (17) of the second section (15) and the first end (12) of the first section (11) is attached to the proximal end (16) of the second section (15), as shown in the surgical configuration of FIG. 5. In one preferred embodiment, the needle is attached by inserting its attaching end (73) into the exterior opening (71) of the hollow inner portion (19) of the second section (15).

The tip of the needle (20) is passed through the endocardium (65) and the left atrial myocardial wall (46) from the endocardial aspect at the right fibrous trigone (37), as shown in FIG. 1A, simultaneously pulling the first (11) and second (15) sections of the ring (10) behind it, such that a portion of the second section (15) eventually passes through the left atrial myocardial wall (46) as in FIG. 1B. The needle (20) is passed in a posterior direction just external to and parallel to the mitral valve annulus (34). The tip of the needle (20) is passed around the outside curvature of the mitral valve annulus (34) and within the fat pad (40) of the atrioventricular groove (39). The needle (20) is moved in a clockwise direction towards the left fibrous trigone (38).

At the left fibrous trigone (38), the needle's tip (72) is passed back through the left atrial myocardial wall (46) from the epicardium (60) and back through the endocardium (65) at the left fibrous trigone (38), thereby pulling the first section (11) into position along the anterior portion (36) and pulling the second section (15) into position within the atrioventricular groove (39) such that the second section (15) is adjacent to the posterior portion (35) of the mitral valve annulus (34), as shown in FIG. 1C.

Referring to FIG. 1D, the annuloplasty ring (10) is sized using the measurement indicia (18) to determine the appropriate length of the second section (15) and hence the appropriate circumference for the annuloplasty ring (10). The distal end (17) can be cut to size, if required, by severing the second section (15) at a selected location on the second section (15). The needle (10) can be removed prior to sizing and/or cutting of the second section (15) or, alternately, it can remain attached to the ring (10) during sizing and/or cutting.

The distal end (17) of the second section (15) is then joined to the second end (13) of the first section (11). In one preferred embodiment as shown in FIG. 1E, the second end (13) and distal end (17) are joined by frictional engagement wherein the second end (13) of the first section (11) is inserted into the hollow inner portion (19) of the second section, until the distal (17) and proximal (16) ends of the second section (15) approach one another approximate a center point on the first section (11).

In another embodiment of the method for implanting the annuloplasty ring, the procedure is reversed in direction, wherein the tip (72) of the needle (20) is first passed through the endocardium (65) and the left atrial myocardial wall (46) from the endocardial aspect at the left fibrous trigone (38) and passed in a posterior direction substantially parallel to the annulus (34). The needle (20) is moved in a counterclockwise direction around the annulus (34) to the right fibrous trigone (37). Here, at the right fibrous trigone (37), the needle's tip (72) is passed back through the left atrial myocardial wall (46) from epicardium (60) and back through the endocardium (65). The procedure then continues as the above procedure is performed in the opposite, counterclockwise direction.

After the annuloplasty ring is in place sutures (80, 81) shown in FIG. 1F can be added to secure the annuloplasty ring to the annulus. A plurality of sutures (80) can be used to fix the ring (10) to the inter-trigone section (36), preferably at the left and right fibrous trigones. Since the inter-trigone section (36) is substantially rigid in the native mitral valve annulus, any scarring that may result from these sutures (80) would not substantially interfere with the normal flexing of the rest of the annulus and movement of the left ventricle.

In addition, at least one suture (81) may be used to fix the second section (15) within the atrioventricular groove (39) as an added precaution for guarding against possible slippage of the ring (10) after it is implanted. This suture (81) would preferably be located near the midpoint of the second section (15).

The preferred embodiments of the present invention allow the mitral valve annulus to maintain its normal flexure, which in turn enables the left ventricle to move in a normal manner as it contracts and relaxes. Furthermore, the method of implanting allows the annuloplasty ring and the annulus, as well, to maintain flexibility indefinitely after the annuloplasty, since it is not necessary to secure the ring in place with a line of sutures through the mitral valve annulus tissue of the posterior portion.

The ring further reestablishes the normal shape and contour of the mitral valve annulus which allows for effective coaptation of the anterior and posterior leaflets of the valve. Additionally, the size and shape of the ring can be adjusted making it easily adaptable to different patients.

In one example, the annuloplasty ring of the present invention can be manufactured using a flexible material that is also elastic to comprise the second section. The elasticity of the ring would accommodate the expansion of the mitral annulus during relaxation of the left ventricle and accommodate contraction of the annulus during contraction of the left ventricle. In other words, the annulus would expand and contract, in addition to flexing, with the expansion and contraction of the left ventricle.

In another example, the first (11) and second (15) sections are joined integrally at the respective first (12) and proximal (16) ends, wherein the first section remains substantially rigid and the second section (15) remains flexible. The integral joining of the two sections can be done by coextrusion, molding or other suitable manufacturing techniques of choice.

Although the present invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

What is claimed is:

1. A method for implanting an annuloplasty ring in a patient's heart, comprising:

implanting a flexible section of the annuloplasty ring in the fat pad of the atrioventricular groove of the heart;

positioning a rigid section of the annuloplasty ring adjacent to the valve annulus; and

forming the annuloplasty ring into a closed loop.

2. The method of claim 1, wherein the annuloplasty ring includes a needle attached to the flexible section.

3. The method of claim 2, wherein the steps of implanting a substantial portion of the annuloplasty ring in the fat pad of the atrioventricular groove further comprises:

inserting the tip of the needle through the endocardium and the left atrial myocardial wall from the endocardial aspect at the right fibrous trigone;

passing the needle and a portion of the annuloplasty ring through the endocardium and the left atrial myocardial wall from the endocardial aspect at the right fibrous trigone;

passing the needle and a portion of the annuloplasty ring in a posterior direction, external to and parallel to the mitral valve annulus; and

inserting the tip of the needle through the left atrial myocardial wall from the epicardial aspect and back through the endocardium at the left fibrous trigone;

passing the needle and a portion of the annuloplasty ring back through the left atrial myocardial wall from the epicardial aspect and back through the endocardium at the left fibrous trigone.

4. The method of claim 3, wherein positioning the rigid section further comprises:

positioning the flexible section in a substantial parallel orientation with the posterior portion of the mitral valve annulus, by pulling the needle;

aligning the rigid section of the annuloplasty ring along an anterior portion of the mitral valve annulus; and

positioning a bow of the rigid section to conform with a contour of the mitral valve annulus adjacent the aortic valve root.

5. The method of claim 4, further comprising:

determining the appropriate size of the annuloplasty ring after implanting and positioning the ring, and before forming the ring into a closed loop; and

cutting the annuloplasty ring to the appropriate size.

6. The method of claim 5, further comprising:

detaching the needle from the annuloplasty ring after implanting and positioning the ring, and before determining the appropriate size.

7. The method of claim 5, wherein the step of forming the annuloplasty ring into a closed loop further comprises:

joining a second end of the rigid section to a distal end of the flexible section by inserting the second end of the rigid section into a hollow inner portion of the distal end of the flexible section.

8. The method of claim 2, further comprising:

suturing the annuloplasty ring to the valve annulus at the left and right fibrous trigones.

9. The method of claim 8, further comprising:

suturing the annuloplasty ring within the fat pad of the atrioventricular groove.

10. A method for implanting an annuloplasty ring in a patient's heart to correct mitral insufficiency in which the mitral valve annulus is restored to a normal shape and flexibility as determined by the movement of the left ventricle, the mitral valve and the mitral valve annulus, the steps comprising:

(1) providing an annuloplasty ring having an elongated flexible section attached at one end to a rigid section with a bow and attached at an opposite end to a round tipped-needle;

(2) inserting a tip of the needle through the endocardium and the left atrial myocardial wall of the heart from the endocardial aspect at the right fibrous trigone;

(3) passing the needle and a portion of the annuloplasty ring through the endocardium and the left atrial myocardial wall of the heart from the endocardial aspect at the right fibrous trigone;

(4) passing the needle and a portion of the annuloplasty ring in a posterior direction just external to and parallel to the mitral valve annulus;

(5) passing the needle and a portion of the annuloplasty ring around the outside of the mitral valve annulus in the fat pad of the atrioventricular groove in a clockwise direction to the left fibrous trigone;

(6) inserting the tip of the needle back through the left atrial myocardial wall and the endocardium from the epicardial aspect at the left fibrous trigone;

(7) passing the needle and a portion of the annuloplasty ring back through the left atrial myocardial wall from the epicardial aspect and back through the endocardium at the left fibrous trigone;

(8) positioning the flexible section substantially parallel to a posterior portion of the mitral valve annulus;

(9) aligning the rigid section along an anterior portion of the mitral valve annulus;

(10) positioning the bow of the rigid section to conform to a contour of the mitral valve annulus adjacent the aortic valve root, and further positioning the flexible section around a posterior portion of the mitral vale annulus;

(11) detaching the needle from the flexible section;

(12) determining the appropriate size of the annuloplasty ring;

(13) cutting the flexible section of the annuloplasty ring to the appropriate size;

(14) closing the annuloplasty ring by affixing the distal end of the flexible section to the second end of the rigid section by inserting the rigid section into the inner hollow portion of the flexible section;

(15) suturing the annuloplasty ring to the valve annulus at the left and right fibrous trigones;

(16) suturing one point along the posterior section of the mitral valve annulus to the flexible section of the annuloplasty ring.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

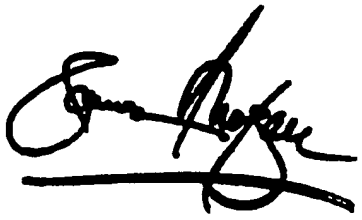
PATENT NO. : 6,250,308 B1
DATED : June 26, 2001
INVENTOR(S) : James L. Cox

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 9,
Line 33, change "4" to -- 2 --.
Line 48, change "2" to -- 1 --.

Signed and Sealed this

Twenty-eighth Day of May, 2002



Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

US006210432B1

(12) **United States Patent**
Solem et al.

(10) **Patent No.: US 6,210,432 B1**
(45) **Date of Patent: Apr. 3, 2001**

(54) **DEVICE AND METHOD FOR TREATMENT OF MITRAL INSUFFICIENCY**

(76) Inventors: **Jan Otto Solem**, Nordmannavägen 20, 237 31 Bjärred; **Per Ola Kimblad**, Saturnusgatan 9, 224 57 Lund, both of (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/345,475**

(22) Filed: **Jun. 30, 1999**

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.15**; 623/1.11; 623/1.16; 623/1.18; 623/1.22

(58) **Field of Search** 623/1.1, 1.11, 623/1.12, 1.15, 1.16, 1.18, 1.2, 1.22

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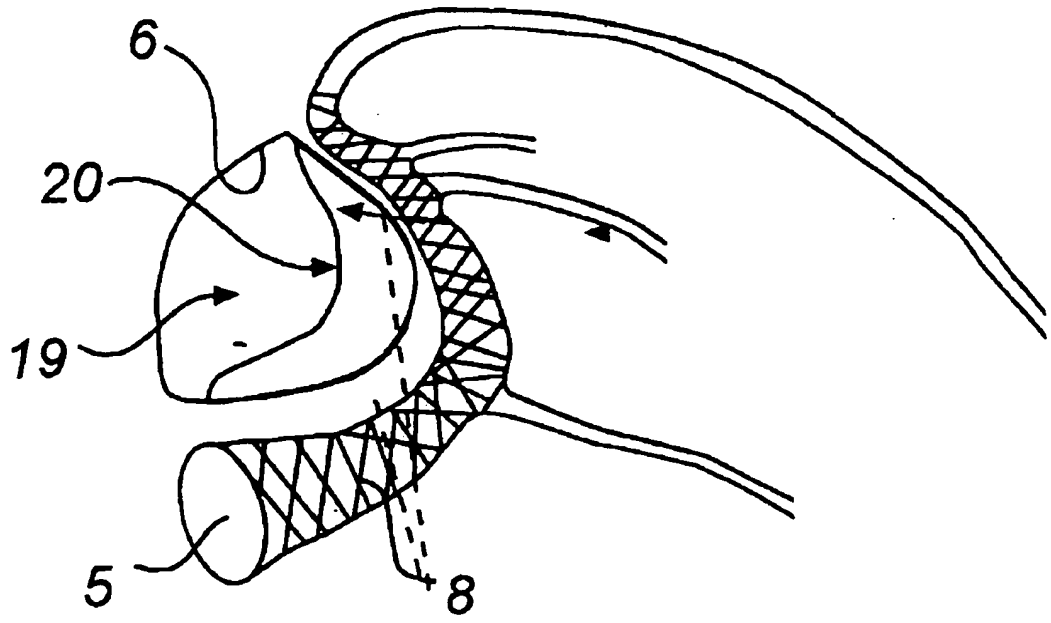
Primary Examiner—Dinh X. Nguyen
(74) *Attorney, Agent, or Firm*—Browdy and Neimark

(57) **ABSTRACT**

A device for treatment of mitral annulus dilatation comprises an elongate body having two states. In a first of these states the elongate body is insertable into the coronary sinus and has a shape adapting to the shape of the coronary sinus. When positioned in the coronary sinus, the elongate body is transferable to the second state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus and the radius of curvature as well as the circumference of the mitral annulus is reduced.

10 Claims, 5 Drawing Sheets



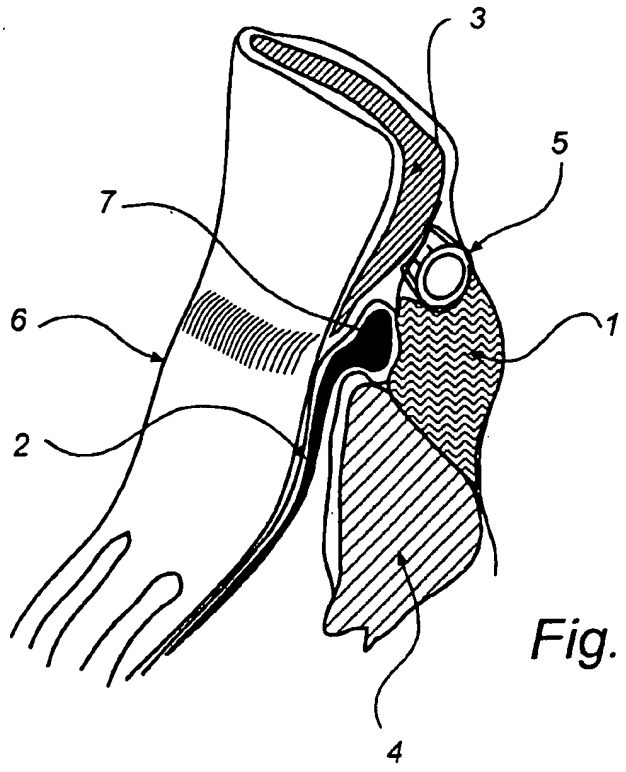


Fig. 1

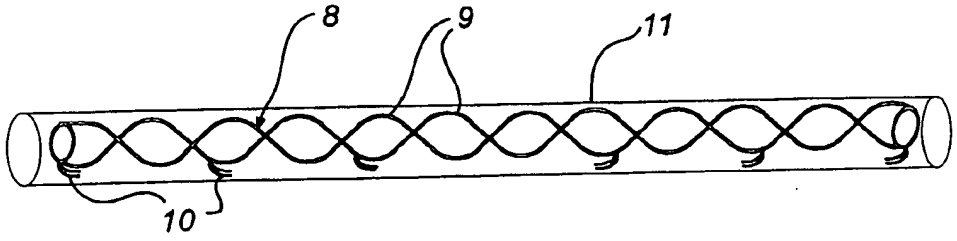


Fig. 2

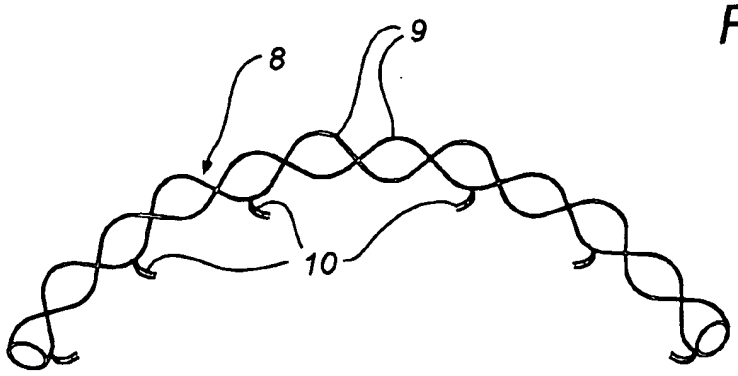


Fig. 3

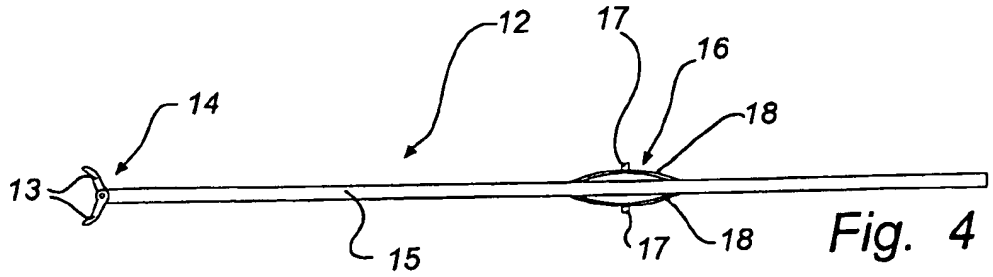


Fig. 4

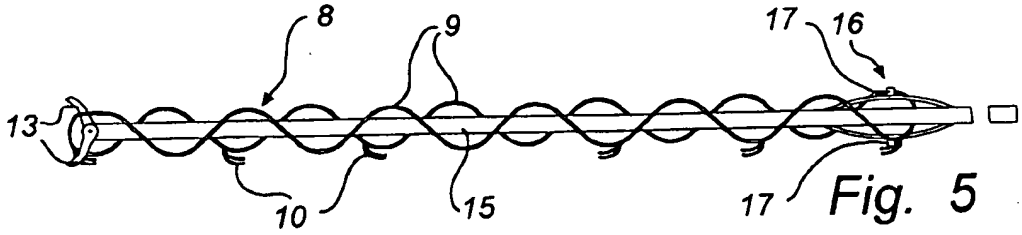


Fig. 5

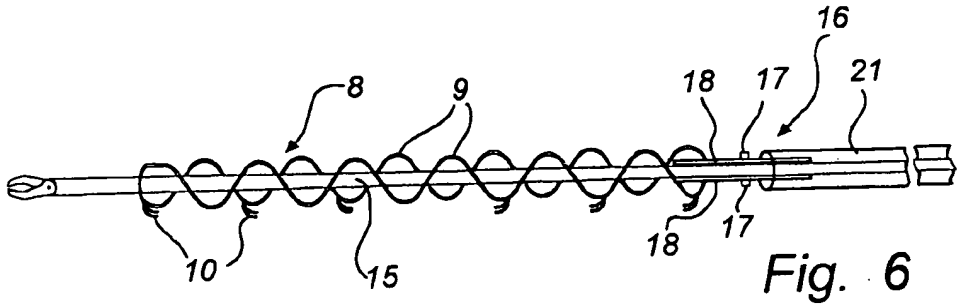


Fig. 6

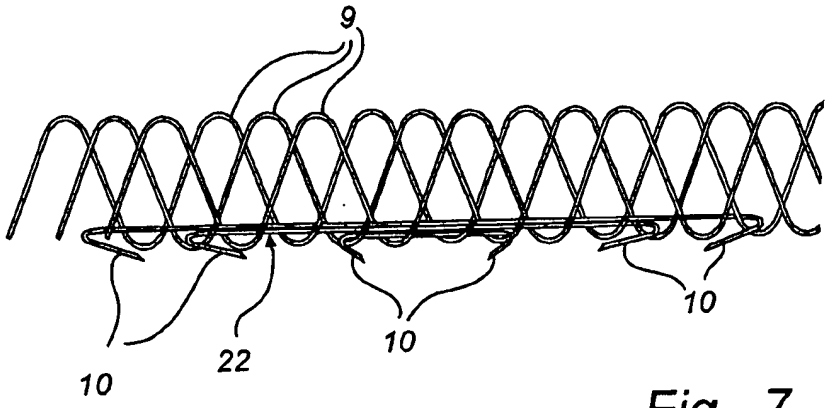


Fig. 7

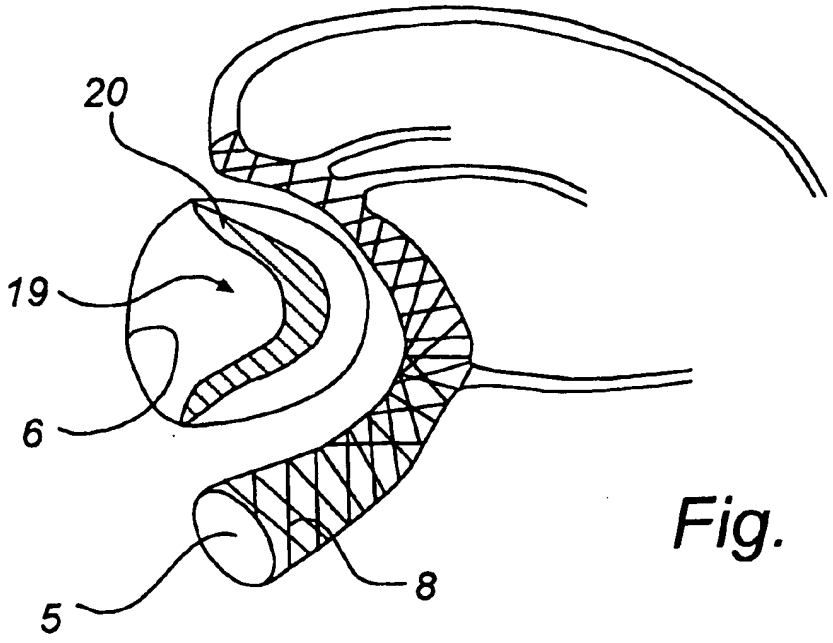


Fig. 8

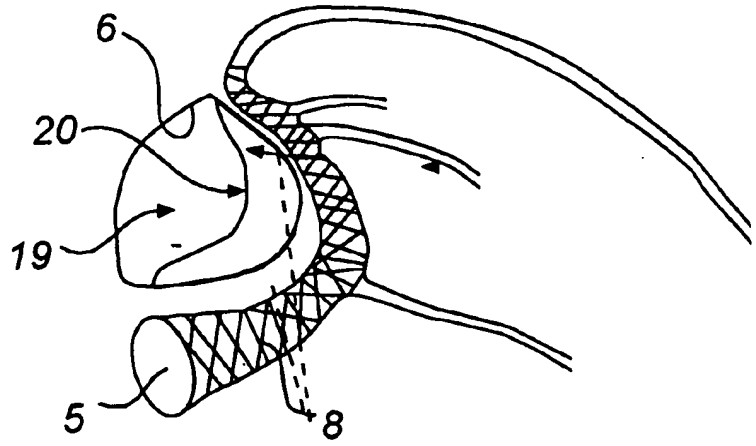


Fig. 9

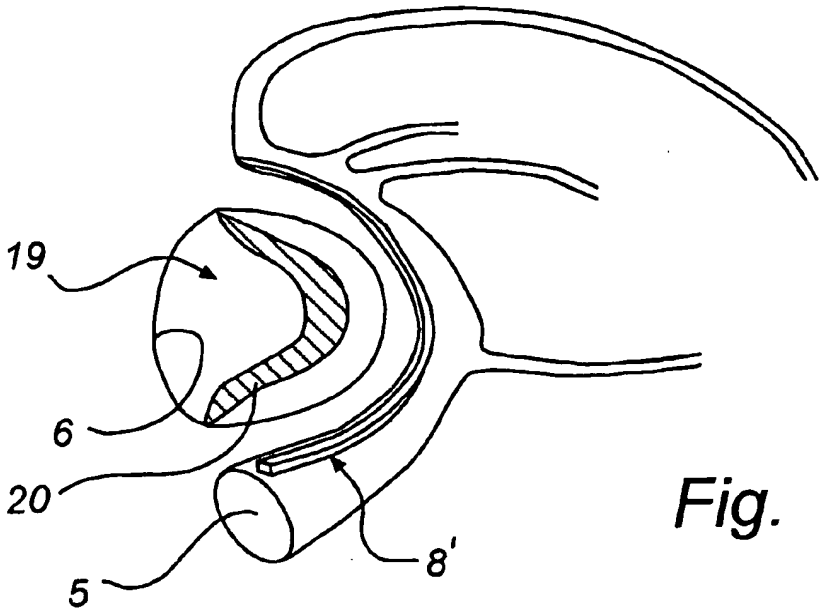


Fig. 10

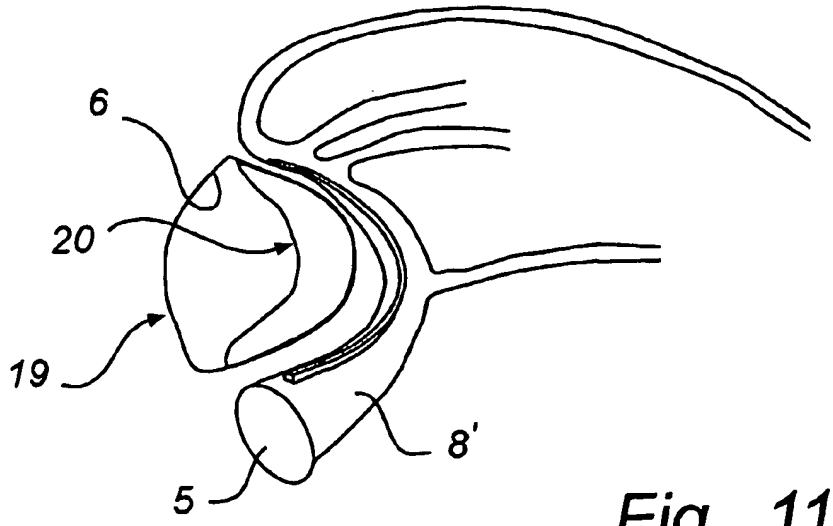


Fig. 11

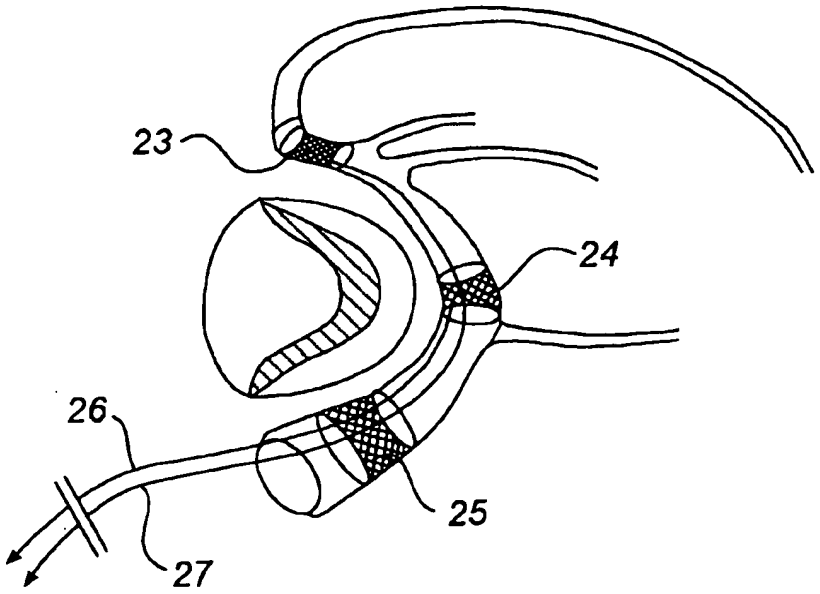


Fig. 12

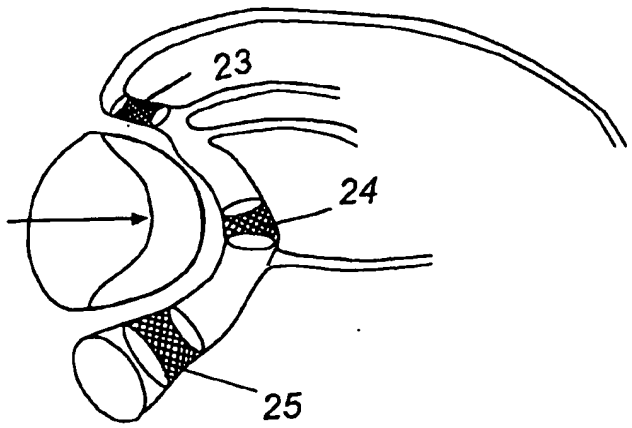


Fig. 13

DEVICE AND METHOD FOR TREATMENT OF MITRAL INSUFFICIENCY

BACKGROUND OF THE INVENTION

The present invention generally relates to a device and a method for treatment of mitral insufficiency and, more specifically, for treatment of dilatation of the mitral annulus.

Mitral insufficiency can result from several causes, such as ischemic disease, degenerative disease of the mitral apparatus, rheumatic fever, endocarditis, congenital heart disease and cardiomyopathy. The four major structural components of the mitral valve are the annulus, the two leaflets, the chordae and the papillary muscles. Any one or all of these in different combinations may be injured and create insufficiency. Annular dilatation is a major component in the pathology of mitral insufficiency regardless of cause. Moreover, many patients have a mitral insufficiency primarily or only due to posterior annular dilatation, since the annulus of the anterior leaflet does not dilatate because it is anchored to the fibrous skeleton of the base of the heart.

Studies of the natural history of mitral insufficiency have found that totally asymptomatic patients with severe mitral insufficiency usually progress to severe disability within five years. At present the treatment consists of either mitral valve replacements or repair, both methods requiring open heart surgery. Replacement can be performed with either mechanical or biological valves.

The mechanical valve carries the risk of thromboembolism and requires anticoagulation, with all its potential hazards, whereas biological prostheses suffer from limited durability. Another hazard with replacement is the risk of endocarditis. These risks and other valve related complications are greatly diminished with valve repair.

Mitral valve repair is theoretically possible if an essentially normal anterior leaflet is present. The basic four techniques of repair include the use of an annuloplasty ring, quadrangular segmental resection of diseased posterior leaflet, shortening of elongated chordae, and transposition of posterior leaflet chordae to the anterior leaflet.

Annuloplasty rings are needed to achieve a durable reduction of the annular dilatation. All the common rings are sutured along the posterior mitral leaflet adjacent to the mitral annulus in the left atrium. The Duran ring encircles the valve completely, whereas the others are open towards the anterior leaflet. The ring can either be rigid, like the original Carpentier ring, or flexible but non-elastic, like the Duran ring or the Cosgrove-Edwards ring.

Effective treatment of mitral insufficiency currently requires open-heart surgery, by the use of total cardiopulmonary by-pass, aortic cross-clamping and cardioplegic arrest.

To certain groups of patient, this is particular hazardous. Elderly patients, patients with a poor left ventricular function, renal disease, severe calcification of the aorta, previous cardiac surgery or other concomitant diseases, would in particular most likely benefit from a less invasive approach, even if repair is not complete. The current trend towards less invasive coronary artery surgery, without cardiopulmonary by-pass, as well as PTCA will also call for a development of a less invasive method for repair of the often concomitant mitral insufficiency.

SUMMARY OF THE INVENTION

Therefore, a first object of the present invention is to provide a device and a method for treatment of mitral insufficiency without the need for cardiopulmonary by-pass and opening of the chest and heart.

A second object of the invention is to provide reduction of the mitral annulus using less invasive surgery.

These and other objects are attained by a device as defined in the appended claim 1, and by a method as defined in the appended claim 7.

According to the present invention, a device for treatment of mitralis insufficiency comprises an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first state of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second state of which the elongate body is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus.

Preferably, means are provided for the transfer of the elongate body to the second state by bending and/or shortening it from a larger radius of curvature to a smaller radius of curvature.

The transfer means may comprise means for bending and/or shortening the elongate body by a preferably asymmetric contraction thereof.

Further, the elongate body may comprise a memory material providing the transfer to the second state.

In a preferred embodiment, the elongate body may comprise a stent. In an alternative embodiment, the device according to the invention may comprise several stent sections and said bending and/or shortening means may comprise wires for shortening the distance between the stent sections.

According to a second aspect, a method of reducing the circumference of the mitral valve annulus comprises the steps of inserting an elongate body into the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, and then providing a bending and/or shortening of the elongate body when positioned in the coronary sinus so as to reduce the curvature of the coronary sinus and thereby reduce the circumference of the mitral valve annulus.

Thus, the present invention takes advantage of the position of the coronary sinus being close to the mitral annulus. This makes repair possible by the use of current catheter-guided techniques.

The coronary veins drain blood from the myocardium to the right atrium. The smaller veins drain blood directly into the atrial cavity, and the larger veins accompany the major arteries and run into the coronary sinus which substantially encircles the mitral orifice and annulus. It runs in the posterior atrioventricular groove, lying in the fatty tissue between the left atrial wall and the ventricular myocardium, before draining into the right atrium between the atrial septum and the post-Eustachian sinus.

In an adult, the course of the coronary sinus may approach within 5–15 mm of the medial attachment of the posterior leaflet of the mitral valve. Preliminary measurements performed at autopsies of adults of normal weight show similar results, with a distance of 5,3±0,6 mm at the medial attachment and about 10 mm at the lateral aspect of the posterior leaflet. The circumference of the coronary sinus was 18,3±2,9 mm at its ostium (giving a diameter of the posterior leaflet of 5,8±0,9 mm) and 9,7±0,6 mm along the lateral aspect of the posterior leaflet (corresponding to a diameter of 3,1±0,2 mm).

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by the following description of preferred embodiments referring to the appended drawings, in which

FIG. 1 is a cross-sectional view of a part of a heart,

FIGS. 2 and 3 are schematic views of a first embodiment of a device according to the present invention,

FIGS. 4–6 are schematic views illustrating an instrument, which may be used when positioning the device shown in FIGS. 2 and 3 in the coronary sinus,

FIG. 7 is a partial, enlarged view of the first embodiment shown in FIG. 2.

FIGS. 8 and 9 are schematic views illustrating the positioning of the device of FIGS. 2 and 3 in the coronary sinus,

FIGS. 10 and 11 are schematic views illustrating the positioning of a second embodiment of the device according to the present invention in the coronary sinus, and

FIGS. 12 and 13 are schematic views illustrating the positioning of a third embodiment of the device according to the present invention in the coronary sinus.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a cross-sectional view through the heart area of the posterior atrioventricular groove **1**, which is filled with fatty tissues. It shows the posterior leaflet **2** of the mitral valve and the adjoining parts **3**, **4** of the atrial myocardium and the ventricular myocardium. The coronary sinus **5** is shown close to the mitral annulus **6** and behind the attachment **7** of the posterior leaflet **2**. Since the coronary sinus **5** substantially encircles the mitral annulus **6**, a reduction of the radius of curvature of the bent coronary sinus **5** also will result in a diameter and circumference reduction of the mitral annulus **6**.

The device of FIG. **2** comprises an elongate body **8** made of memory metal, e.g. Nitinol, or other similar material which has a memory of an original shape, illustrated in FIG. **3**, and can be temporary forced into another shape, illustrated in FIG. **2**. This elongate body **8** comprises one, two or more memory metal strings **9** of helical or other shape so as to fit together and be able of permitting the movements described below. Along the elongate body **8** several hooks **10** are fastened so as to extend radially out therefrom. These hooks **10** are covered by a cover sheet **11** in FIG. **2**.

The elongate body **8** is forced into a stretched or extended state by means of a stabilizing instrument **12** shown in FIG. **4**. This instrument **12** has two arms **13** at a distal end **14** of a rod **15** and a locking means **16** at a proximal end of the rod **15**. The distance between the ends of the rod **15** corresponds to the desired length of the elongate body **8** when being inserted into the coronary sinus **5**.

The arms **13** are free to move between the position shown in FIG. **4** and a position in alignment with the rod **15**, as shown in FIG. **6**. The locking means **16** has two locking knobs **17**, which are pressed radially outwards from the rod **15** by two spring blades **18**. Thus, the elongated body **8** can be pushed over the rod **15** of the stabilizing instrument **12**, then stretched between the arms **13** and the knobs **17**, and finally locked in its stretched state on the stabilizing instrument **12** between the arms **13** and the knobs **17**, as illustrated in FIG. **5**.

The rod **15** may be a metal wire which is relatively stiff between the distal end **14** and the locking means **16** but still so bendable that it will follow the shape of the coronary sinus **5**. Proximally of the locking means **16** the metal wire of the stabilizing instrument **11** is more pliable to be able to easily follow the bends of the veins.

The above-described elongate body **8** is positioned in the coronary sinus **5** in the following way:

An introduction sheet (not shown) of synthetic material may be used to get access to the venous system. Having reached access to the venous system, a long guiding wire (not shown) of metal is advanced through the introduction sheet and via the venous system to the coronary sinus **5**. This guiding wire is provided with X-ray distance markers so that the position of the guiding wire in the coronary sinus **5** may be monitored.

The elongate body **8** is locked onto the stabilizing instrument **12**, as shown in FIG. **5**, and introduced into the long cover sheet **11** of synthetic material. This aggregate is then pushed through the introduction sheet and the venous system to the coronary sinus **5** riding on the guiding wire. After exact positioning of the elongate body **8** in the coronary sinus **5**, as illustrated in FIG. **8** where the mitral valve **19** is shown having central gap **20**, the cover sheet **11** is retracted exposing the elongate body **8** within the coronary sinus **5**. This maneuver allows the hooks **10** on the elongate body **8** to dig into the walls of the coronary sinus **5** and into the heart. The elongate body **8** is still locked on to the stabilizing instrument **12** such that the hooks **10** engage the walls of the coronary sinus **5** in the stretched or extended state of the elongate body **8**.

A catheter **21**, shown in FIG. **6**, is pushed forward on the guiding wire and the rod **15** for releasing the elongate body **8** from the locking means **16** by pressing the spring blades **18** towards the rod **15**. This movement releases the knobs **17** as well as the arms **13** from engagement with the elongate body **8** which contracts as illustrated in FIG. **9** and as a result bends towards the mitral valve annulus **6** moving the posterior part thereof forward (shown by arrows in FIG. **9**). This movement reduces the circumference of the mitral valve annulus **6** and thereby closes the central gap **20**.

FIG. **7** illustrates a part of an arrangement of the wires **9** and the hooks **10** along a peripheral part of the elongate body **8**, whereby the elongate body **8** will be asymmetrically contracted resulting in a bending thereof when interconnecting parts **22** of at least some of the hooks **10** are shortened to an original shape.

FIGS. **10** and **11** illustrate an alternative embodiment of an elongate body **8'**, which is a solid wire in the shape of an open U-shaped ring that will engage the wall of the coronary sinus **5** most adjacent to the mitral valve annulus **6** when inserted into the coronary sinus **5**. The elongate body **8'** consists of a memory metal material which when reverting to its original shape will bend as illustrated in FIG. **11**. The return of the open ring **8'** to its original shape may be initiated in several ways, as is obvious to the man skilled in the art.

The third embodiment of the elongate body **8"**, illustrated in FIGS. **12** and **13**, comprises three stent sections **23–25** positioned at one end of the elongate body **8"**, at the middle thereof and at the other end of the elongate body **8"**, respectively. These stent sections **23–25** may be positioned in the coronary sinus **5** as illustrated by conventional means, such that their positions are fixed. They are connected by wires **26**, **27**, which may be maneuvered from outside the vein system such that the distances between the adjacent stent sections **23**, **24** and **24**, **25** are reduced. More specifically, these distances are reduced asymmetrically, i.e. more on the side of coronary sinus **5** most adjacent to the

posterior part of the mitral valve annulus 6. Thereby, the elongate body 8" is bent, as illustrated in FIG. 13, and presses the coronary sinus 5 against the mitral valve annulus 6 closing the gap 20.

Concludingly, the present invention provides a device placed in the coronary sinus, designed to reduce the dilatation of the mitral annulus. This device is at a distance from the attachment of the posterior leaflet that does not much exceed the distance at which present annuloplasty rings are placed by open surgery techniques, and the coronary sinus is along its entire course large enough to hold such a device. The device could be positioned by catheter technique or any other adequate technique and offers a safer alternative to the current open surgery methods. The device could be designed or heparin-coated so as to avoid thrombosis in the coronary sinus, thus reducing the need for aspirin, ticlopedine or anticoagulant therapy.

It is to be understood that modifications of the above-described device and method can be made by people skilled in the art without departing from the spirit and scope of the invention.

What is claimed is:

1. A device for treatment of mitral annulus dilatation, comprising an elongate body having such dimensions as to be insertable into the coronary sinus and having two states, in a first of which the elongate body has a shape that is adaptable to the shape of the coronary sinus, and to the second of which the elongate body is transferable from the said first state assuming a reduced radius of curvature, whereby the radius of curvature of the coronary sinus is reduced as well as the circumference of the mitral valve annulus, when the elongate body is positioned in the coronary sinus.

2. A device according to claim 1, further comprising means for the transfer of the elongate body to the second state by bending and shortening it from a larger radius of curvature to a smaller radius of curvature.

3. A device according to claim 2, wherein said transfer means comprises means for bending and shortening the elongate body by a contraction thereof.

4. A device according to claim 1, wherein the elongate body comprises a memory material providing the transfer to the second state.

5. A device according to claim 1, wherein the elongate body comprises a stent.

6. A device according to claim 2, wherein the elongate body comprises several stent sections and said bending means comprises wires for shortening the distance between the stent sections.

7. A method of reducing the circumference of the mitral valve annulus, comprising inserting an elongate body into the coronary sinus in the vicinity of the posterior leaflet of the mitral valve, and providing a bending and shortening of the elongate body when positioned in the coronary sinus so as to reduce the curvature of the coronary sinus and thereby reduce the radius of circumference of the mitral valve annulus.

8. A method according to claim 7, wherein said bending and shortening of the elongate body is provided by a contraction thereof.

9. A method according to claim 7, wherein a memory material is used in the elongate body for providing the transfer to the second state.

10. A method according to claim 7, wherein the elongate body is made from several stent sections and wires are used for shortening the distance between the stent sections in order to bend the elongate body.

* * * * *

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(54) BODY LUMEN DEVICE ANCHOR, DEVICE AND ASSEMBLY

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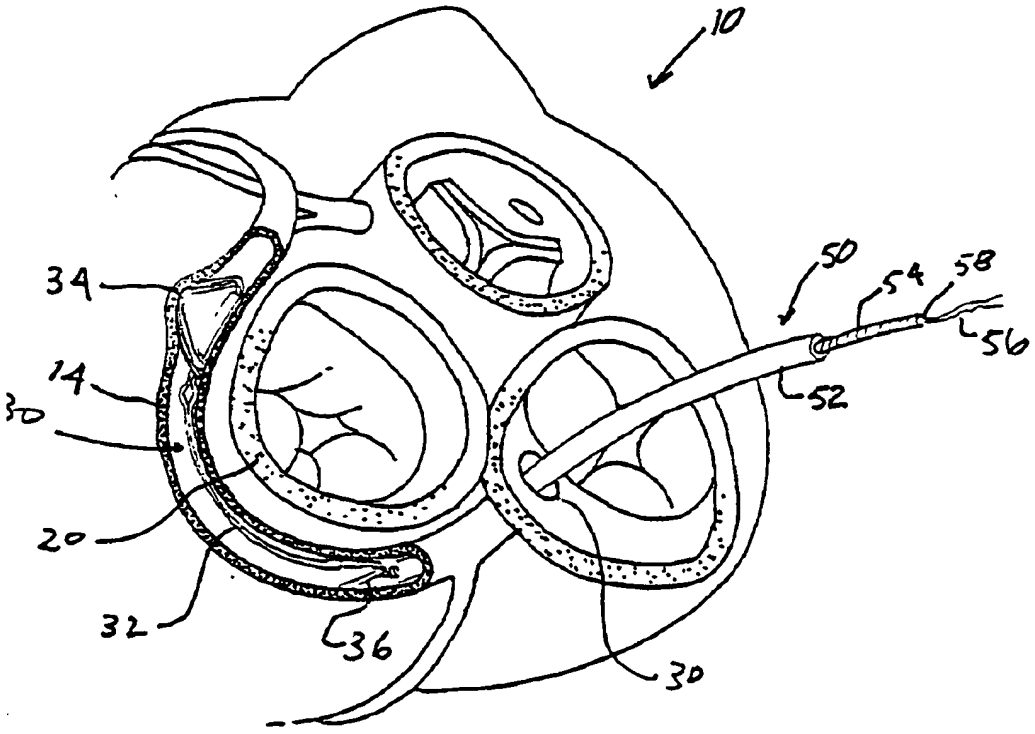
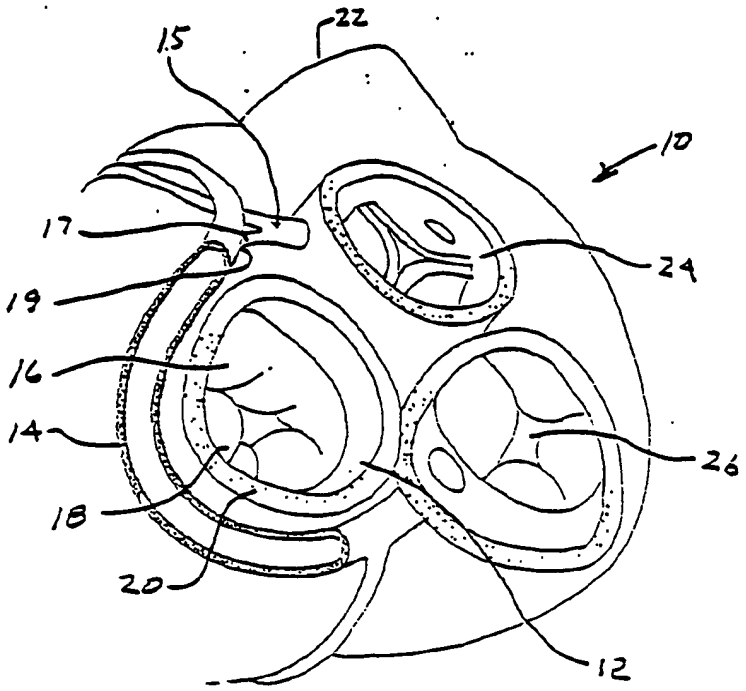
(57) ABSTRACT

An anchor anchors a therapeutic device having an elongated body within a body lumen. The anchor includes a fixation member carried on the device which is adjustable from a first configuration that permits placement of the device in the body lumen to a second configuration that anchors the device within the body lumen. The anchor further includes a lock that locks the fixation member in the second configuration. The fixation member may be locked in any one of a plurality of intermediate points between the first configuration and a maximum second configuration.




15
22
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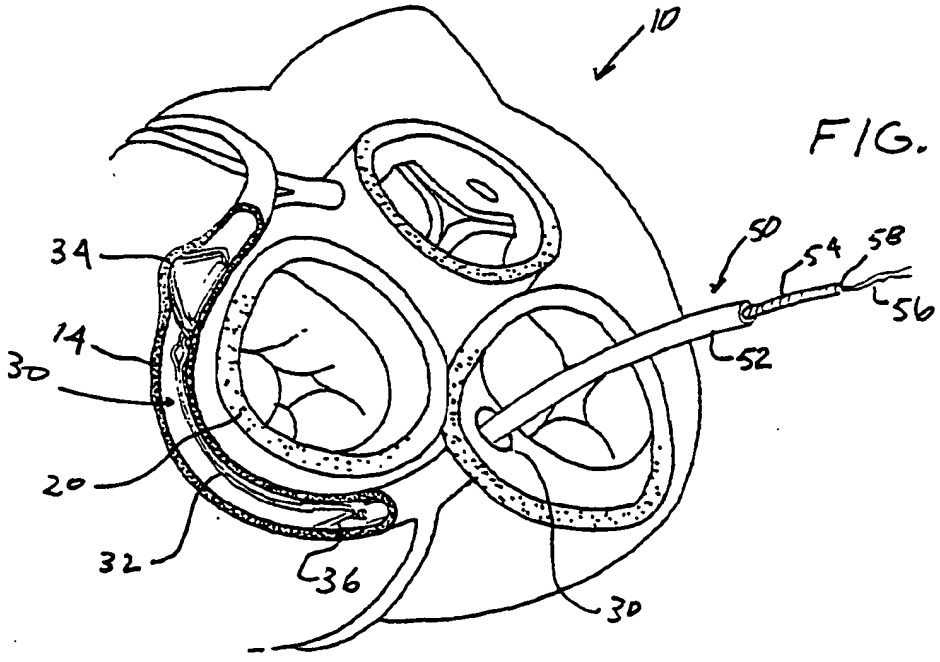
20
12

FIG. 1


10
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36
30

FIG. 2

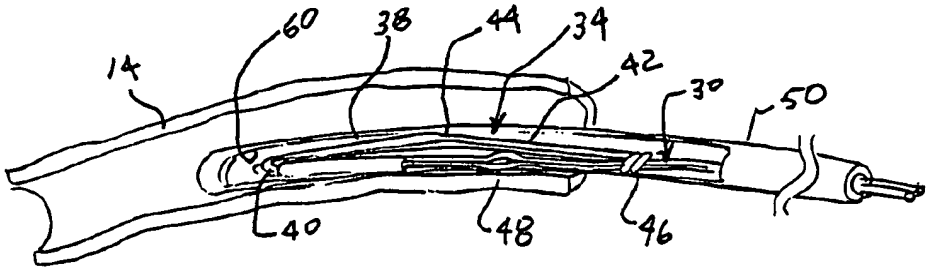

FIG. 3

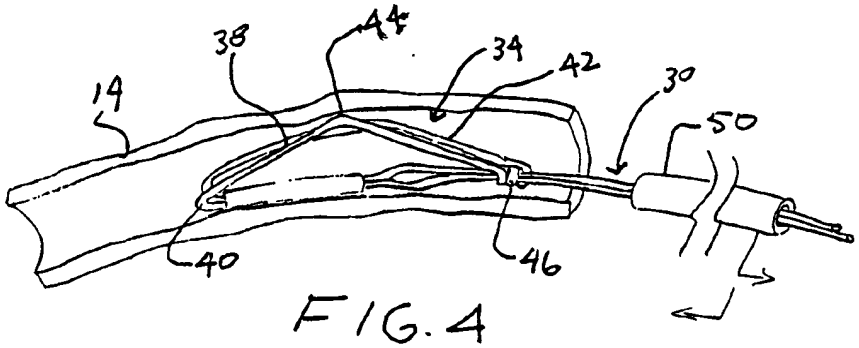

FIG. 4

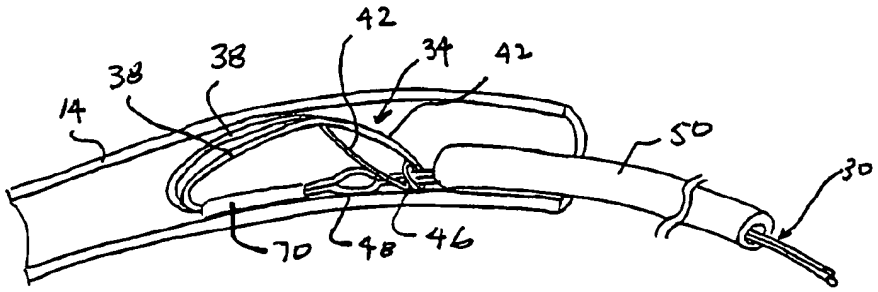

FIG. 5

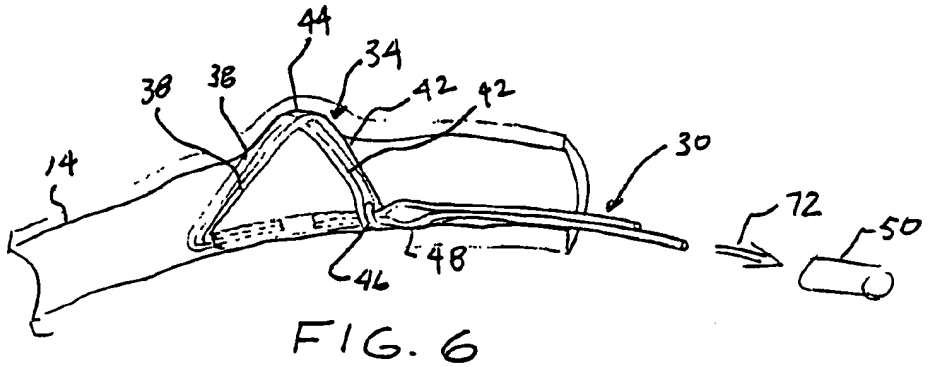

FIG. 6

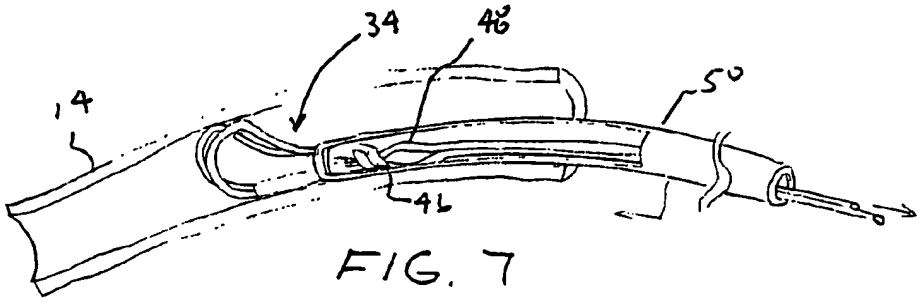

FIG. 7

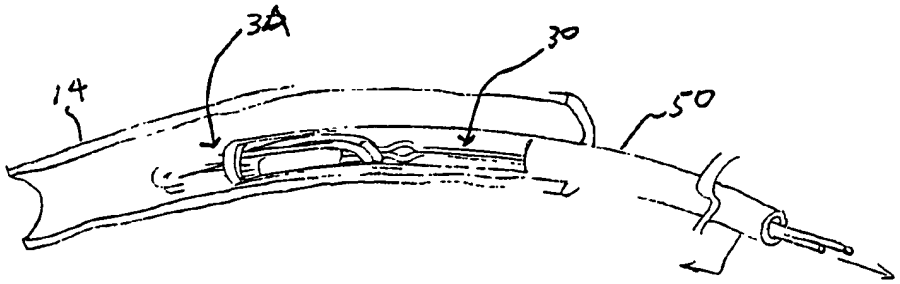

FIG. 8

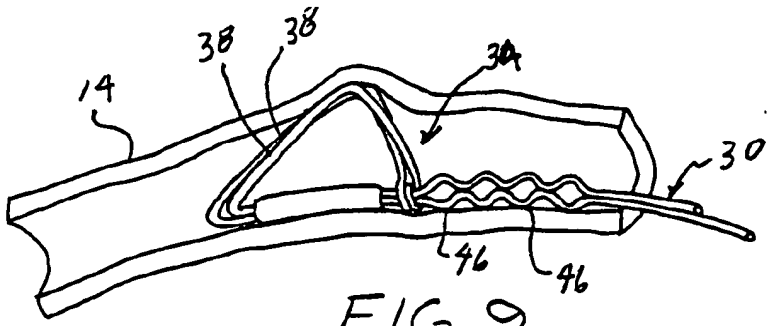

FIG. 9

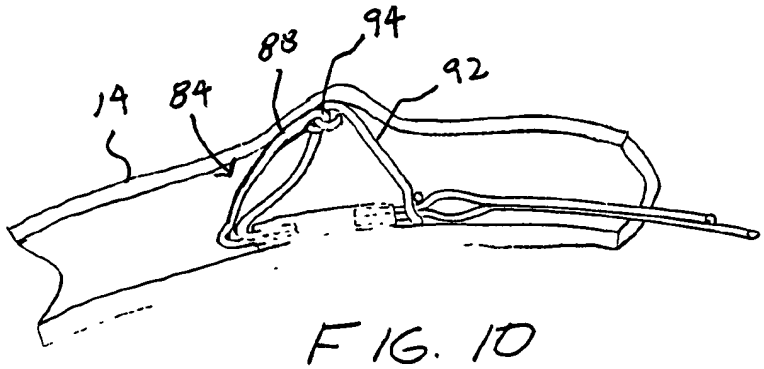

FIG. 10

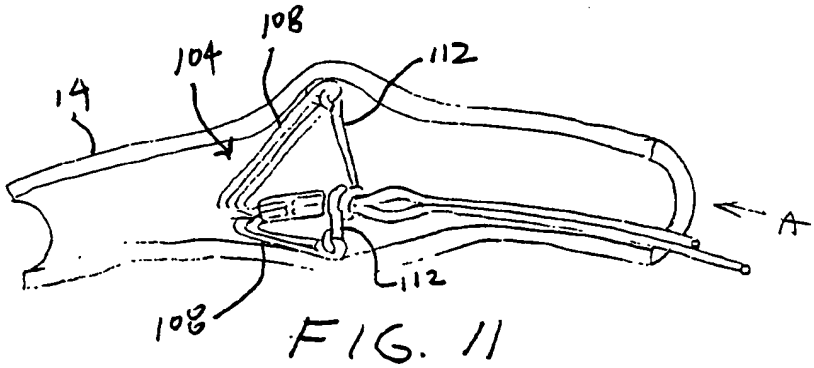

FIG. 11

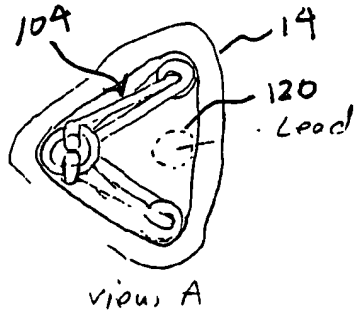

FIG. 12

BODY LUMEN DEVICE ANCHOR, DEVICE AND ASSEMBLY

FIELD OF THE INVENTION

[0001] The present invention generally relates to an anchor for use with a device which requires anchoring in a body lumen. The present invention more particularly relates to a mitral valve annulus device and assembly wherein the device is deployed and anchored in the coronary sinus of a heart adjacent the mitral valve annulus to reshape the mitral valve annulus.

BACKGROUND OF THE INVENTION

[0002] The human heart generally includes four valves. Of these valves, a most critical one is known as the mitral valve. The mitral valve is located in the left atrial ventricular opening between the left atrium and left ventricle. The mitral valve is intended to prevent regurgitation of blood from the left ventricle into the left atrium when the left ventricle contracts. In preventing blood regurgitation the mitral valve must be able to withstand considerable back pressure as the left ventricle contracts.

[0003] The valve cusps of the mitral valve are anchored to muscular wall of the heart by delicate but strong fibrous cords in order to support the cusps during left ventricular contraction. In a healthy mitral valve, the geometry of the mitral valve ensures that the cusps overlie each other to preclude regurgitation of the blood during left ventricular contraction.

[0004] The normal functioning of the mitral valve in preventing regurgitation can be impaired by dilated cardiomyopathy caused by disease or certain natural defects. For example, certain diseases may cause dilation of the mitral valve annulus. This can result in deformation of the mitral valve geometry to cause ineffective closure of the mitral valve during left ventricular contraction. Such ineffective closure results in leakage through the mitral valve and regurgitation. Diseases such as bacterial inflammations of the heart or heart failure can cause the aforementioned distortion or dilation of the mitral valve annulus. Needless to say, mitral valve regurgitation must not go uncorrected.

[0005] One method of repairing a mitral valve having impaired function is to completely replace the valve. This method has been found to be particularly suitable for replacing a mitral valve when one of the cusps has been severely damaged or deformed. While the replacement of the entire valve eliminates the immediate problem associated with a dilated mitral valve annulus, presently available prosthetic heart valves do not possess the same durability as natural heart valves.

[0006] Various other surgical procedures have been developed to correct the deformation of the mitral valve annulus and thus retain the intact natural heart valve function. These surgical techniques involve repairing the shape of the dilated or deformed valve annulus. Such techniques, generally known as annuloplasty, require surgically restricting the valve annulus to minimize dilation. Here, a prosthesis is typically sutured about the base of the valve leaflets to reshape the valve annulus and restrict the movement of the valve annulus during the opening and closing of the mitral valve.

[0007] Many different types of prostheses have been developed for use in such surgery. In general, prostheses are annular or partially annular shaped members which fit about the base of the valve annulus. The annular or partially annular shaped members may be formed from a rigid material, such as a metal, or from a flexible material.

[0008] While the prior art methods mentioned above have been able to achieve some success in treating mitral regurgitation, they have not been without problems and potential adverse consequences. For example, these procedures require open heart surgery. Such procedures are expensive, are extremely invasive requiring considerable recovery time, and pose the concomitant mortality risks associated with such procedures. Moreover, such open heart procedures are particularly stressful on patients with a compromised cardiac condition. Given these factors, such procedures are often reserved as a last resort and hence are employed late in the mitral regurgitation progression. Further, the effectiveness of such procedures is difficult to assess during the procedure and may not be known until a much later time. Hence, the ability to make adjustments to or changes in the prostheses to obtain optimum effectiveness is extremely limited. Later corrections, if made at all, require still another open heart surgery.

[0009] An improved therapy to treat mitral regurgitation without resorting to open heart surgery has recently been proposed. This is rendered possible by the realization that the coronary sinus of a heart is near to and at least partially encircles the mitral valve annulus and then extends into a venous system including the great cardiac vein. As used herein, the term "coronary sinus" is meant to refer to not only the coronary sinus itself but in addition, the venous system associated with the coronary sinus including the great cardiac vein. The therapy contemplates the use of a device introduced into the coronary sinus to reshape and advantageously effect the geometry of the mitral valve annulus.

[0010] The device includes a resilient member having a cross sectional dimension for being received within the coronary sinus of the heart and a longitudinal dimension having an unstressed arched configuration when placed in the coronary sinus. The device partially encircles and exerts an inward pressure on the mitral valve. The inward pressure constricts the mitral valve annulus, or at least a portion of it, to essentially restore the mitral valve geometry. This promotes effective valve sealing action and eliminates mitral regurgitation.

[0011] The device may be implanted in the coronary sinus using only percutaneous techniques similar to the techniques used to implant cardiac leads such as pacemaker leads. One proposed system for implanting the device includes an elongated introducer configured for being releasably coupled to the device. The introducer is preferably flexible to permit it to advance the device into the heart and into the coronary sinus through the coronary sinus ostium. To promote guidance, an elongated sheath is first advanced into the coronary sinus. Then, the device and introducer are moved through a lumen of the sheath until the device is in position within the coronary sinus. Because the device is formed of resilient material, it conforms to the curvatures of the lumen as it is advanced through the sheath. The sheath is then partially retracted to permit the device to assume its

unstressed arched configuration. Once the device is properly positioned, the introducer is then decoupled from the device and retracted through the sheath. The procedure is then completed by the retraction of the sheath. As a result, the device is left within the coronary sinus to exert the inward pressure on the mitral valve to restore mitral valve geometry.

[0012] The foregoing therapy has many advantages over the traditional open heart surgery approach. Since the device, system and method may be employed in a comparatively noninvasive procedure, mitral valve regurgitation may be treated at an early stage in the mitral regurgitation progression. Further, the device may be placed with relative ease by any minimally invasive cardiologist. Still further, since the heart remains completely intact throughout the procedure, the effectiveness of the procedure may be readily determined. Moreover, should adjustments be deemed desirable, such adjustments may be made during the procedure and before the patient is sent to recovery.

[0013] Another approach to treat mitral regurgitation with a device in the coronary sinus is based upon the observation that the application of a localized force against a discrete portion of the mitral valve annulus can terminate mitral regurgitation. This suggests that mitral regurgitation may be localized and nonuniform. Hence, the device applies a force to one or more discrete portions of the atrial wall of the coronary sinus to provide localized mitral valve annulus reshaping instead of generalized reshaping of the mitral valve annulus. Such localized therapy would have all the benefits of the generalized therapy. In addition, a localized therapy device may be easier to implant and adjust.

[0014] A still further approach to treat mitral regurgitation from the coronary sinus of the heart contemplates a device having a first anchor configured to be positioned within and fixed to the coronary sinus of the heart adjacent the mitral valve annulus within the heart, a cable fixed to the first anchor and extending proximally from the first anchor within the heart, a second anchor configured to be positioned in and fixed in the heart proximal to the first anchor and arranged to slidingly receive the cable, and a lock that locks the cable on the second anchor. When the first and second anchors are fixed within the heart, the cable may be drawn proximally and locked on the second anchor. The geometry of the mitral valve is thereby effected. This approach provides flexibility in that the second anchor may be positioned and fixed in the coronary sinus or alternatively, the second anchor may be positioned and fixed in the right atrium. This approach further allows adjustments in the cable tension after implant.

[0015] A still further alternative for treating mitral regurgitation contemplates a device having a first anchor configured to be positioned within and anchored to the coronary sinus of the heart adjacent the mitral valve annulus within the heart. A second anchor is configured to be positioned within the heart proximal to the first anchor and adjacent the mitral valve annulus within the heart. A connecting member, having a fixed length, is permanently attached to the first and second anchors. As a result, when the first and second anchors are within the heart with the first anchor anchored in the coronary sinus, the second anchor may be displaced proximally to effect the geometry of the mitral valve annulus and released to maintain the effect on the mitral valve geometry. The second anchor may be configured, when deployed, to anchor against distal movement but be moveable proximally to permit the second anchor to be displaced proximally within the coronary sinus.

[0016] A further device that effects the condition of a mitral valve annulus of a heart also includes an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus. Here, the elongated member is flexible when placed in the heart in a first orientation to position the device in the coronary sinus adjacent the mitral valve annulus and relatively inflexible when rotated into a second orientation after the device is positioned in the coronary sinus adjacent to the mitral valve annulus.

[0017] The device thus has a first radius of curvature when in the first orientation and a second and greater radius of curvature when in the second orientation to effect the mitral valve geometry. Once positioned and in the second orientation, the device is anchored against both longitudinal and rotational movement.

[0018] Devices, other than those described above may be placed in body lumens other than the coronary sinus for therapeutic effect. All such devices must be anchored against movement when deployed at least for an acute phase until the natural body mechanisms produce sufficient fibrotic tissue about the devices for permanent fixation. While the device anchors must protect against device movement, they must also allow ready deployment to facilitate device implant. However, it is desirable that the anchors also be readily releasable, at least during the acute phase to permit device position adjustment or even device removal if required. All of these factors are especially important for devices implanted in the heart because of the potential need for precise device positioning during implant and the extreme movement of the heart during heartbeats.

SUMMARY OF THE INVENTION

[0019] The invention provides an anchor that anchors a device having an elongated body in a body lumen. The anchor includes a fixation member carried on the device, the fixation member being adjustable from a first configuration that permits placement of the device in the body lumen to a second configuration that anchors the device within the body lumen, and a lock that locks the fixation member in the second configuration.

[0020] The lock is releasable to release the fixation member from the second configuration to permit the device to be removed from the body lumen. The fixation member may also be deformable to permit the device to be moved within the body lumen.

[0021] The fixation member is adjustable from the first configuration to a maximum second configuration. The lock may be configured to lock the fixation member at any one of a plurality of intermediate points between the first configuration and the maximum second configuration.

[0022] The fixation member may be elongated and have a first end hingedly coupled to the device body. The fixation member may thus extend along the device body closely spaced to the device body when in the first configuration and be pivoted from the device body to the second configuration to engage and anchor the device in the body lumen.

[0023] The anchor may further include a support that renders the fixation member substantially rigid when in the second configuration. The support may be an extension of the fixation member, wherein the fixation member includes a second end opposite the first end and wherein the lock locks the fixation member second end on the device body.

[0024] The fixation member may include a second end opposite the first end. The support may include a support member having a first end hingedly coupled to the fixation member second end and a second end opposite the support member first end. The lock may lock the support member second end on the device body. The support member second end may be slidable along the device body. The anchor may include a plurality of the fixation members and/or a plurality of support members.

[0025] The invention further provides a device that effects the condition of a mitral valve annulus of a heart. The device includes an elongated body dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus. The device further includes a fixation member carried by the device, the fixation member being adjustable from a first configuration that permits placement of the device in the coronary sinus to a second configuration that anchors the device within the coronary sinus, and a lock that locks the fixation member in the second configuration.

[0026] The lock is releasable to release the fixation member from the second configuration to permit the device to be moved within the coronary sinus. The fixation member may be deformable to permit the device to be moved within the coronary sinus.

[0027] The fixation member may be adjustable from the first configuration to a maximum second configuration and the lock may lock the fixation member at any one of a plurality of intermediate points between the first configuration and the maximum second configuration.

[0028] The fixation member is elongated and has a first end hingedly coupled to the device body. The fixation member may extend along the device body closely spaced to the device body when in the first configuration and may be pivoted from the device body when in the second configuration to engage the coronary sinus and anchor the device in the coronary sinus. The device may further include a support that renders the fixation member substantially rigid when in the second configuration. The support may be an extension of the fixation member, wherein the fixation member includes a second end opposite the first end and wherein the lock locks the fixation member second end on the device body. The fixation member second end may be slidable along the device body and the device may include a plurality of the fixation members.

[0029] The fixation member may include a second end opposite the first end. The support may be a separate support member having a first end hingedly coupled to the fixation member second end and second end opposite the support member first end. The lock may then lock the support member second end on the device body. The support member second end may be slidable along the device body. The device may include a plurality of the fixation members and support members.

[0030] The invention further provides an assembly that effects the condition of a mitral valve annulus of a heart. The assembly includes a mitral valve therapy device dimensioned to be placed in the coronary sinus adjacent the mitral valve annulus. The device includes an elongated body, a fixation member carried by the device, the fixation member being adjustable from a first configuration that permits placement of the device in the coronary sinus to a second configuration that anchors the device within the coronary sinus, and a lock that locks the fixation member in the second configuration. The assembly further includes a flexible catheter having a lumen that receives the device and being dimensioned to be advanced into the coronary sinus to place the device adjacent the coronary sinus.

[0031] The assembly may further include an elongated pusher that is received by the lumen of the catheter proximal to the device and that permits the device and the catheter to be moved opposite each other. The assembly may further include a tether receivable by the catheter lumen and engagable with the device to pull the device distally with respect to the catheter. The catheter may be used to transition the fixation member from the first configuration to the second configuration. For example, the fixation member may be elongated and have a first end hingedly coupled to the device body. The fixation member may then extend along the device body when in the first configuration and the fixation member may be pivoted from the device body into the second configuration by distal movement of the catheter with respect to the device to cause the fixation member to engage the coronary sinus and anchor the device in the coronary sinus.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further aspects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[0033] **FIG. 1** is a superior view of a human heart with the atria removed;

[0034] **FIG. 2** is a superior view of a human heart similar to **FIG. 1** illustrating a mitral valve therapy device including an anchor embodying the present invention deployed therein along with an assembly embodying the present invention for deploying the device;

[0035] **FIG. 3** is a side view with portions cut away illustrating a first step in deploying the device anchor of the device of **FIG. 2**;

[0036] **FIG. 4** is a side view similar to **FIG. 3** illustrating a further step in the deployment of the anchor embodying the present invention;

[0037] **FIG. 5** is a side view similar to **FIG. 3** illustrating a further step in the deployment of the device anchor;

[0038] **FIG. 6** is a side view similar to **FIG. 3** illustrating the deployed device anchor;

[0039] **FIG. 7** is a side view similar to **FIG. 3** illustrating a first step in the removal of the device anchor;

[0040] **FIG. 8** is a side view similar to **FIG. 3** illustrating a final step in the removal of the device anchor;

[0041] FIG. 9 is a side view similar to FIG. 3 illustrating an alternate embodiment of a deployed device anchor embodying the present invention;

[0042] FIG. 10 is a side view similar to FIG. 3 illustrating a further embodiment of a deployed device anchor embodying the present invention;

[0043] FIG. 11 is a side view similar to FIG. 3 illustrating a still further embodiment of a deployed device anchor embodying the present invention; and

[0044] FIG. 12 is an end view of FIG. 11.

DETAILED DESCRIPTION OF THE INVENTION

[0045] Referring now to FIG. 1, it is a superior view of a human heart 10 with the atria removed to expose the mitral valve 12, the coronary sinus 14, the coronary artery 15, and the circumflex artery 17 of the heart 10 to lend a better understanding of the present invention. Also generally shown in FIG. 1 are the pulmonary valve 22, the aortic valve 24, and the tricuspid valve 26 of the heart 10.

[0046] The mitral valve 12 includes an anterior cusp 16, a posterior cusp 18 and an annulus 20. The annulus encircles the cusps 16 and 18 and maintains their spacing to provide a complete closure during a left ventricular contraction. As is well known, the coronary sinus 14 partially encircles the mitral valve 12 adjacent to the mitral valve annulus 20. As is also known, the coronary sinus is part of the venus system of the heart and extends along the AV groove between the left atrium and the left ventricle. This places the coronary sinus essentially within the same plane as the mitral valve annulus making the coronary sinus available for placement of the mitral valve therapy device of the present invention therein.

[0047] FIG. 2 shows a mitral valve therapy device 30 embodying the present invention shown deployed in the coronary sinus 14 of the heart 10 adjacent the mitral valve annulus 20 for effecting the geometry of the mitral valve annulus. Also shown in FIG. 2 is a deployment system 50 that deploys the device 30 in the coronary sinus 14. The device 30 takes the form of an elongated body 32 which includes a distal anchor 34 embodying the present invention and a proximal anchor 36.

[0048] The anchors 34 and 36 are shown in FIG. 2 in their deployed configuration. As will be seen hereinafter, upon deployment of the device 30 in the coronary sinus, the distal anchor 34 is transitioned from a first configuration to a locked second configuration. In the process, it is expanded outwardly to anchor the device in the coronary sinus against both bidirectional longitudinal and rotational movement. The proximal anchor however, when deployed, is configured to permit proximal movement. This allows the device 30 to be tightened within the coronary sinus by proximal pulling of the anchor 36 after the distal anchor 34 is deployed. The device 30 may be formed from Nitinol or stainless steel, for example.

[0049] The deployment system 50 illustrated in FIG. 2 includes an elongated catheter 52, an elongated pusher 54, and a tether 56. In deploying the device 30, the tether 56 is first looped about the proximal anchor 36 of the device 30 as illustrated and the device is then loaded into the catheter 50. The tether 56 is then threaded through an internal lumen 58 of the pusher 54 and looped around the proximal anchor 36 of the device 30 as illustrated. The pusher 54 is then advanced along the tether 56 for engaging the device 30 and pushing the device distally down the catheter to a predetermined position at the distal end of the catheter 50. The catheter with the device 30 loaded therein is then fed into the heart and through the coronary sinus ostium 30 into the coronary sinus to place the catheter in a position such that the device 30 is adjacent the mitral valve annulus 20. Thereafter, the device is maintained in a stationary position by the pusher 54 as the catheter 50 is partially withdrawn to expose the distal anchor 34. Once the distal anchor is exposed, it is deployed by the catheter in a manner to be described more particularly with respect to FIGS. 3-6. Once the distal anchor 34 is deployed, the catheter 50 is then retracted proximally of the proximal anchor 36. This exposes the proximal anchor 36 and permits the proximal anchor to self deploy. Once the proximal anchor is deployed, the tether 56 is pulled proximally to move the proximal anchor 36 in a proximal direction for tightening the device within the coronary sinus and to an extent which results in the desired effect on the geometry of the mitral valve annulus 20. During this adjustment process, mitral regurgitation may be monitored and the device adjusted for optimal results. When the device 30 is in its final position within the coronary sinus 14, the pusher 54 and catheter 50 may be removed from the heart. The tether 56 may be permitted to remain in the heart during an acute phase to ascertain the effectiveness of the device 30. Should further adjustment of the device be necessary, the tether 56 may then be used as a guide for guiding the introduction of the catheter 50 back into the heart.

[0050] FIGS. 3-6 illustrate the manner in which the distal anchor 34 may be deployed in the coronary sinus 14 for anchoring the device 30. It will be appreciated by those skilled in the art, of course, that the anchor 34 may be utilized in body lumens other than the coronary sinus and with therapeutic devices other than the mitral valve annulus therapy device illustrated in FIG. 2.

[0051] In each of FIGS. 3-6 a portion of the coronary sinus has been removed and the pusher has not been illustrated so as to not unduly complicate the figures. FIG. 3 shows the catheter 50 disposed within the coronary sinus 14 with the device 30 and distal anchor within the catheter 50. To that end, the catheter includes a lumen 60 which is dimensioned to receive the device 30 and the distal anchor 34 when the distal anchor 34 is in a first configuration. The distal anchor 34 includes an elongated fixation member 38 which is hingedly coupled to the distal end of the device 30 at a hinge 40. The elongated fixation member thus extends along the body of the device 30. The fixation member includes a support 42 which is an extension of the fixation member 38 and which is hingedly connected to the fixation member 38 at a hinge point 44. The proximal end of the fixation member 38 includes a loop 46 which is looped about the device 30 to permit the loop 46 to slide along the device 30. As will be seen subsequently, the loop 46 forms part of a lock for locking the anchor 34 in a second configuration for anchoring in the coronary sinus.

[0052] To complete the anchor, the device 30 includes a resilient enlarged portion 48 over which the loop 46 may slide. Once the loop 46 is located distally of the enlarged

portion **48**, it will be held by the enlarged portion **48** for locking the device in the second configuration.

[0053] **FIG. 4** illustrates the anchor **34** after the catheter **50** has been moved proximal to the anchor **34**. More specifically, it will be noted that the distal end of the catheter **50** is now proximal to the loop **46** or proximal end of the anchor **34**. The shape memory of the anchor has caused the anchor to expand and is now partially transitioned from the first configuration of **FIG. 3** to the second and final configuration to be described with reference to **FIG. 6** subsequently.

[0054] **FIG. 5** illustrates the anchor **34** being transitioned from the first configuration to the second configuration. This transition is implemented by the distal end of the catheter **50** pushing the proximal end of the anchor **34** in the distal direction. To maintain the position of the anchor **34** during the transition, the tether **56** is used to hold the device **30** against distal movement.

[0055] The particular configuration of the distal anchor **34** in accordance with this embodiment may be more particularly seen in **FIG. 5**. Here it may be seen that the distal anchor is formed of a wire having a first end secured to the distal end of the device **30**, folded back and looped around the device and then back to the distal end of the device. Both ends of the anchor are then crimped by a crimp **70**. This configuration results in a pair of fixation members **38** each having a support extension **42**. In addition, the fixation members **38** may be formed so as to have a loop configuration to maximize surface contact with the inner wall of the coronary sinus **14**.

[0056] As the catheter **50** is moved distally, it forces the loop **46** of the anchor **34** over the enlarged portion **48** of the device **30** to a point distal to the enlarged portion **48**. This locks the loop **46** distally of the enlarged portion **48** for locking the anchor **34** in an enlarged second configuration as illustrated in **FIG. 6** to anchor the device **30** within the coronary sinus **14**. More specifically, it may be seen that the supports **42** have been pivoted at the hinge **44** relative to the fixation member **38**. This allows the fixation members **38** to be supported by the supports **42** and securely locked by the lock of the loop **46** and enlarged portion **48** of the device **30**. The fixation members **38** provide broad surface contact with the inner wall of the coronary sinus **14**. This provides for anchoring within the coronary sinus of the device **30** against both bidirectional longitudinal and rotational movement. Once the anchor **34** is deployed as illustrated in **FIG. 6**, the catheter **50** may then be removed as indicated by the arrow **72**.

[0057] One of the many features of the anchor of the instant invention is that it may be moved within or removed from the body lumen in which it is deployed. More specifically, and making reference to **FIG. 6**, the anchor **34** may be removed by grabbing the support members **42** and pulling the loop **46** over the resilient enlarged portion **48** of the device **30**. When the loop **46** is on the proximal side of the enlarged portion **48**, further proximal movement of the loop **46** will fully transition the anchor **34** from the second configuration back to the first configuration for removal within the catheter **50**.

[0058] Alternatively, by virtue of the support members, the anchor **34** may be formed of deformable material such as stainless steel. Using this to advantage, the anchor **34** may be partially collapsed by the catheter **50** to permit the anchor **34** and hence the device **30** to be moved and repositioned in the coronary sinus after which the resilience of the anchor material returns the anchor to its locked and deployed configuration. The anchor may be collapsed by the catheter **50** as illustrated in **FIGS. 7 and 8**.

[0059] In **FIG. 7**, it will be noted that the catheter **50**, while the device is held stationary by the tether, is moved distally over the enlarged portion **48** and the loop **46**. The anchor **34** is now partially collapsed for movement and repositioning. Once repositioned, the catheter may be withdrawn to redeploy the anchor **34** which returns to its second configuration by virtue of its resiliency and shape memory.

[0060] As seen in **FIG. 8**, continued distal movement of the catheter **50** causes the anchor **34** to fully collapse. This allows the anchor **34** to be totally drawn into the catheter **50**. Once the anchor **34** is collapsed and within the catheter **50**, the device **30** may be removed by removing the catheter with the device therein or by pulling the device proximally through the catheter.

[0061] FIGS. **9-12** illustrate alternative embodiments of the anchor of the present invention. These embodiments are once again illustrated in connection with the anchoring of a mitral valve annulus therapy device within the coronary sinus of a heart.

[0062] In **FIG. 9**, the device **30** is shown having a plurality of enlarged portions **46**. As a result, a plurality of locks are provided on the device **30** to enable the fixation members to be locked at any one of a plurality of intermediate points between the first configuration and a maximum second configuration illustrated in **FIG. 9**. This enables the anchor **34** to be sized to a given body lumen.

[0063] **FIG. 10** shows another anchor **84** embodying the present invention which has a separate fixation member **88** and support member **92**. The second or distal end of the fixation member **88** is hingedly coupled to a first or distal end of the support member **92** by a hinged connection **94**. The fixation member **88** may have a hoop configuration as the fixation members **38** previously described.

[0064] **FIGS. 11 and 12** illustrated a still further anchor **104** having a pair of fixation members **108** and corresponding separate support members **112**. Here, the fixation members **108** are formed by immediately adjacent anchor wires which, as best seen in **FIG. 12**, are disposed at an angle to permit a cardiac lead, indicated by the dashed circle **120**, to pass through the anchor and thus be within the coronary sinus. Hence, a device having an anchor such as anchor **104** is compatible with the provision of a cardiac lead therewith.

[0065] As can thus been seen, the present invention provides a new and improved anchor for anchoring a therapeutic device within a body lumen. The anchor of the present invention, by virtue of the lockable support member, creates mechanical advantage to assist deployment of the anchor. This also increases anchor strength. Because the support members may be of hooped or looped configuration, increased contact area between the anchor and the body lumen can be achieved. In addition, the anchor of the present invention allows deactivation and repositioning of the anchor or therapeutic device incorporating the anchor. Still further, because of the locked support structure, the anchor

may be formed of smaller diameter wire, tube wall, or other materials which without the locked support provided by the anchor of the present invention would be unsuitable for this application.

[0066] While particular embodiments of the present invention have been shown and described, modifications may be made. It is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

What is claimed:

1. A device that effects the condition of a mitral valve annulus of a heart comprising:

an elongated body dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus;

a fixation member carried by the device, the fixation member being adjustable from a first configuration that permits placement of the device in the coronary sinus to a second configuration that anchors the device within the coronary sinus; and

a lock that locks the fixation member in the second configuration.

2. The device of claim 1 wherein the lock is releasable to release the fixation member from the second configuration to permit the device to be moved within the coronary sinus.

3. The device of claim 1 wherein the fixation member is deformable to permit the device to be moved within the coronary sinus.

4. The device of claim 1 wherein the fixation member is adjustable from the first configuration to a maximum second configuration and wherein the lock locks the fixation member intermediate the first configuration and the maximum second configuration.

5. The device of claim 4 wherein the lock locks the fixation member at any one of a plurality of intermediate points between the first configuration and the maximum second configuration.

6. The device of claim 1 wherein the fixation member is elongated and has a first end hingedly coupled to the device body, wherein the fixation member extends along the device body closely spaced to the device body when in the first configuration and wherein the fixation member is pivoted from the device body when in the second configuration to engage the coronary sinus and anchor the device in the coronary sinus.

7. The device of claim 6 further comprising a support that renders the fixation member substantially rigid when in the second configuration.

8. The device of claim 7 wherein the support is an extension of the fixation member, wherein the fixation member includes a second end opposite the first end and wherein the lock locks the fixation member second end on the device body.

9. The device of claim 8 wherein the fixation member second end is slidable along the device body.

10. The device of claim 8 wherein the device comprises a plurality of the fixation members.

11. The device of claim 7 wherein the fixation member includes a second end opposite the first end, wherein the support comprises a support member having a first end hingedly coupled to the fixation member second end, wherein the support member has a second end opposite the support member first end, and wherein the lock locks the support member second end on the device body.

12. The device of claim 11 wherein the support member second end is slidable along the device body.

13. The device of claim 11 wherein the device comprises a plurality of the fixation members and support members.

14. An assembly that effects the condition of a mitral valve annulus of a heart, the assembly comprising:

a mitral valve therapy device dimensioned to be placed in the coronary sinus adjacent the mitral valve annulus, the device including an elongated body, a fixation member carried by the device, the fixation member being adjustable from a first configuration that permits placement of the device in the coronary sinus to a second configuration that anchors the device within the coronary sinus, and a lock that locks the fixation member in the second configuration; and

a flexible catheter having a lumen that receives the device and being dimensioned to be advanced into the coronary sinus to place the device adjacent the coronary sinus.

15. The assembly of claim 14 wherein the fixation member is adjustable from the first configuration to a maximum second configuration and wherein the lock locks the fixation member intermediate the first configuration and the maximum second configuration.

16. The assembly of claim 15 wherein the lock locks the fixation member at any one of a plurality of intermediate points between the first configuration and the maximum second configuration.

17. The assembly of claim 14 further comprising an elongated pusher that is received by the lumen of the catheter proximal to the device and that permits the device and the catheter to be moved opposite each other.

18. The assembly of claim 14 further comprising a tether receivable by the catheter lumen and engagable with the device to pull the device distally with respect to the catheter.

19. The assembly of claim 18 wherein the catheter transitions the fixation member from the first configuration to the second configuration.

20. The assembly of claim 19 wherein the fixation member is elongated and has a first end hingedly coupled to the device body, wherein the fixation member extends along the device body when in the first configuration and wherein the fixation member is pivoted from the device body into the second configuration by distal movement of the catheter with respect to the device to engage the coronary sinus and anchor the device in the coronary sinus.

21. The assembly of claim 20 wherein the device further comprises a support that renders the fixation member substantially rigid when in the second configuration.

22. The assembly of claim 21 wherein the support is an extension of the fixation member, wherein the fixation member includes a second end opposite the first end and wherein the lock locks the fixation member second end on the device body when the fixation member second end is in a locked position.

23. The assembly of claim 22 wherein the fixation member second end is slidable along the device body by the catheter into the locked position.

24. The assembly of claim 22 wherein the device comprises a plurality of the fixation members.

25. The assembly of claim 21 wherein the fixation member includes a second end opposite the first end, wherein the support comprises a support member having a first end hingedly coupled to the fixation member second end, wherein the support member has a second end opposite the support member first end, and wherein the lock locks the support member second end on the device body when the support member second end is in a locked position.

26. The assembly of claim 25 wherein the support member second end is slidable along the device body by the catheter into the locked position.

27. The assembly of claim 26 wherein the device comprises a plurality of the fixation members and support members.

28. The assembly of claim 14 wherein the lock is releasable to release the fixation member from the second configuration to permit the device to be removed from the coronary sinus.

29. The assembly of claim 14 wherein the fixation member is deformable to permit the device to be moved within the coronary sinus.

30. An anchor that anchors, in a body lumen, a device having an elongated body dimensioned to be placed in the body lumen, the anchor comprising:

a fixation member carried on the device, the fixation member being adjustable from a first configuration that permits placement of the device in the body lumen to a second configuration that anchors the device within the body lumen; and

a lock that locks the fixation member in the second configuration.

31. The anchor of claim 30 wherein the lock is releasable to release the fixation member from the second configuration to permit the device to be moved within the body lumen.

32. The anchor of claim 30 wherein the fixation member is deformable to permit the device to be moved within the body lumen.

33. The anchor of claim 30 wherein the fixation member is adjustable from the first configuration to a maximum second configuration and wherein the lock locks the fixation member intermediate the first configuration and the maximum second configuration.

34. The anchor of claim 33 wherein the lock locks the fixation member at any one of a plurality of intermediate points between the first configuration and the maximum second configuration.

35. The anchor of claim 30 wherein the fixation member is elongated and has a first end hingedly coupled to the device body, wherein the fixation member extends along the device body closely spaced to the device body when in the first configuration and wherein the fixation member is pivoted from the device body when in the second configuration to engage the body lumen and anchor the device in the body lumen.

36. The anchor of claim 35 further comprising a support that renders the fixation member substantially rigid when in the second configuration.

37. The anchor of claim 36 wherein the support is an extension of the fixation member, wherein the fixation member includes a second end opposite the first end and wherein the lock locks the fixation member second end on the device body.

38. The anchor of claim 37 wherein the fixation member second end is slidable along the device body.

39. The anchor of claim 37 comprising a plurality of the fixation members.

40. The anchor of claim 36 wherein the fixation member includes a second end opposite the first end, wherein the support comprises a support member having a first end hingedly coupled to the fixation member second end, wherein the support member has a second end opposite the support member first end, and wherein the lock locks the support member second end on the device body.

41. The anchor of claim 40 wherein the support member second end is slidable along the device body.

42. The anchor of claim 40 comprising a plurality of the fixation members and support members.

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